Review to Inform the Strategic Direction of Laboratory Medicine

January 2024

“The purpose of this review is to inform the development of a strategic, integrated approach to develop a sustainable and scalable future for laboratory services.”

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Background and Context

Chair Foreword

The HSE is responsible for the provision of health and personal social care services in Ireland. Diagnostics are not just central but at the heart of how effective health care services are delivered. Taking both significant and ongoing rapid advancements across the healthcare spectrum into account, it is no surprise that our laboratories must not just keep pace but make every possible endeavour to plan ahead; collectively we have a responsibility to harness new opportunities and serve our customers, the service users.

This review, informing the strategic direction of our national laboratories, is an important piece of work. The voices of Medical Scientists, Clinical Scientists, Clinical Biochemists and Pathologists have been heard and their views shared.

A steering group led a number of working groups where a number of questions were addressed: namely to map and understand the rationale behind current structures and practices, to consider the impact of professional development pathways, to look at the vast array of scientific developments available/on the way through and seek valuable insights.

It is clear that many valuable opportunities can be progressed, albeit subject to overall HSE prioritisation, planning and value for money. Integration and oversight through a “hub and spoke” model which could support centres of excellence, differentiation for specialised testing and flexibility to take full advantage of developments in the genetics/genomics space offers many opportunities.

Our steering and working groups have delved into the detail and I commend their work. This document sets out where we are and where we would like to be, leaving it now to the penning of a strategic document which will offer a pathway to how this can be achieved. In this regard, it is also acknowledged that there are wider interdependencies to be taken into consideration.

To the steering and working groups, it has been my honour to work with you. Our work involved a range of complex discussions, where establishing the facts in itself was challenging. Throughout this project, I witnessed scientists and clinicians facing many difficult questions as we looked to the future the future and reaching a consensus, taking complex infrastructures and legacy processes into account.

I thank Dr. Colm Henry, Dr. Siobhán Ní Bhriain, Dr. Fraser Thompson (Deloitte), Danielle Farrelly and the entire steering group for your guidance throughout.

Patricia Byron
Chairperson

Welcome from Dr. Colm Henry, Chief Clinical Officer, HSE

Laboratory-based clinical services play a key role in the detection and management of disease and in ensuring patient safety and public health. HSE laboratory-based multidisciplinary teams are managing the opportunities and challenges associated with rapid advances in understanding of health and disease and changing analytical and information technologies. They are doing so at a time when it is exceptionally difficult to recruit and retain people with the requisite skills and qualifications. They are operating, in many cases, from buildings that were designed and built for a different era.

In this context, I invited representatives of key professional groups that have developed and sustained laboratory services to work collaboratively with the chairperson of this working group to capture their perspectives on current opportunities and challenges. The purpose was to inform the development of a strategic, integrated approach to develop a sustainable and scalable future for laboratory services.

I am grateful to all those who have contributed for their work in developing this document. It provides a valuable summary of those opportunities and challenges from the perspective of those professional groups who contributed. The perspective is set out in four sections dealing with current services and structures, education and credentialing pathways, scientific and technological advances, and relevant international models. There is a strong and appropriate emphasis throughout this document on the people in those professions whom we depend on to develop and deliver these services. Their training, skills and commitment are the foundation of the service. Their aspirations for their professions and their service are clearly articulated in this document. I am pleased to accept this document as one key contribution towards the development of a sustainable and scalable future for laboratory services, and I look forward to continued engagement with these professional groups and other stakeholders as we work towards that strategic, integrated approach to develop a sustainable and scalable future for laboratory services.

Dr. Colm Henry
Chief Clinical Officer, HSE

Welcome from Dr. Siobhán Ni Bhriain, National Clinical Director Integrated Care, HSE

It is with great pleasure and a sense of pride that I introduce this comprehensive Review to Inform the Strategic Direction of Laboratory Medicine. As we navigate the intricate landscape of scientific exploration and technological advancement, the collaborative spirit and collective intelligence exhibited by the colleagues who participated have truly set the stage for ground-breaking achievements.

The pages that follow encapsulate the essence of our shared commitment to excellence, innovation, and the pursuit of knowledge. The success of any scientific endeavour lies not only in the excellence of individual work, but also in the synergy of collaborative efforts. In this context, the series of meetings held in the past months and last 2 years have served to improve our shared understanding of the work and roles of those in Laboratory services in Ireland.

I want to extend my heartfelt gratitude to all the colleagues who actively participated in these deliberations. Your unwavering dedication, expertise, and passion have been instrumental in propelling our collective vision forward. The dynamic discussions and constructive debates during these meetings exemplify the importance of developing a collaborative ethos, demonstrating that the value of identifying synergies and working together.

Thank you to all our colleagues for your considered contributions and a very particular thanks to Patricia Byron, who chaired the group with commitment, integrity and perseverance. Patricia fostered an environment where views were exchanged and a common understanding developed that will help to shape the future of Laboratory Services. A very big thanks also to Fraser and Danielle, who kept us on track with our meetings, our notes and the final product, taking account of the feedback, changes and many suggestions that were made during the course of the work.

Siobhán Ni Bhriain

Dr. Siobhán Ni Bhriain
National Clinical Director Integrated Care, HSE

Glossary of Terms

Acronym	Meaning
ACBI	Association of Clinical Biochemists in Ireland
ACSLM	Academy of Clinical Science and Laboratory Medicine
CCO	Chief Clinical Officer
CHO	Community Health Organisation
CPD	Continuing Professional Development
DOH	Department of Health
DP	Digital Pathology
DRG	Diagnostic Related Groups
ECDC	European Centre for Disease Prevention and Control
EFLM	European Federation of Clinical Chemistry and Laboratory Medicine
EHR	Electronic Health Record
EMA	European Medicines Agency
EQA	External Quality Assurance
EUspLM	European Specialist in Laboratory Medicine
HG	Hospital Group
HPRA	Health Products Regulatory Authority
HR	Health Region
HRB	Health Research Board
HSCP	Health and Social Care Professional
HSE	Health Service Executive
IACS	Irish Association of Clinical Scientists
ICT	Information and Communications Technology
IEQAS	Irish External Quality Assessment Scheme
IQC	Internal Quality Control
IRC	Irish Research Council
KPI	Key Performance Indicator
LIMS	Laboratory Information Management System
MDT	Multi-disciplinary Teams
MLA	Medical Laboratory Aide
MSC	Managed Service Contract

Acronym	Meaning
NCCP	National Cancer Control Programme
NCHD	Non-Consultant Hospital Doctor
NDTP	National Doctors Training and Planning
NGS	Next Generation Sequencing
NHS	National Health Service (UK)
NPT	Near-Patient Testing
NSS	National Screening Service
NVRL	National Virus Reference Laboratory
OECD	Organisation for Economic Co-operation and Development
PHMVL	Public Health Microbiology and Virus Laboratories
QA	Quality Assurance
RCPI	Royal College of Physicians of Ireland
SFI	Science Foundation Ireland
SLA	Service Level Agreement
STP	Scientist Training Programme
TAT	Turnaround Times
UCD	University College Dublin
WHO	World Health Organisation
WTE	Whole Time Equivalent

Executive Summary

The evolving landscape of population health and the surge in chronic diseases necessitates a robust, interconnected, and adaptable clinical laboratory diagnostic service to meet emerging healthcare demands. The recent SARS-CoV-2 pandemic underscored the pivotal role of laboratory medicine in patient care and the effective management of healthcare systems. Providing accurate testing guidance, timely results, and expert clinical insights is pivotal in directing patients to appropriate care levels, specialties, and facilities. Trust in the delivered results is therefore paramount, given the critical decisions which frequently hinge on the data provided. Beyond the delivery of results, laboratory medicine embodies the cornerstone of value-based care, which is demonstrated by the multi-faceted role it plays in the healthcare sector. In addition to being a linchpin of effective and safe patient care, laboratory medicine also plays a pivotal role in research, resource stewardship, public health, quality assurance, and more.

In March 2022, a National Working Group was established to *Inform the Strategic Direction of Laboratory Medicine*. The overarching purpose of the group was to undertake a review to inform a strategic, integrated approach to developing laboratory services, which will in turn enable and enhance healthcare reform. The review focuses on four key areas which are seen as critical to informing the development of a strategic approach:

1. Map out current services and structures with a focus on national services to identify and understand the current practice in pathology departments.
2. Consider education and credentialing pathways to support professional development of laboratory staff with a broad-based educational approach that is reflective of their area of competence and expertise and aligned to evolving best practice standards and service requirements.
3. Review of scientific and technologically enabled advances in laboratory medicine.
4. Consider relevant international models of care and lessons learned to inform future direction.

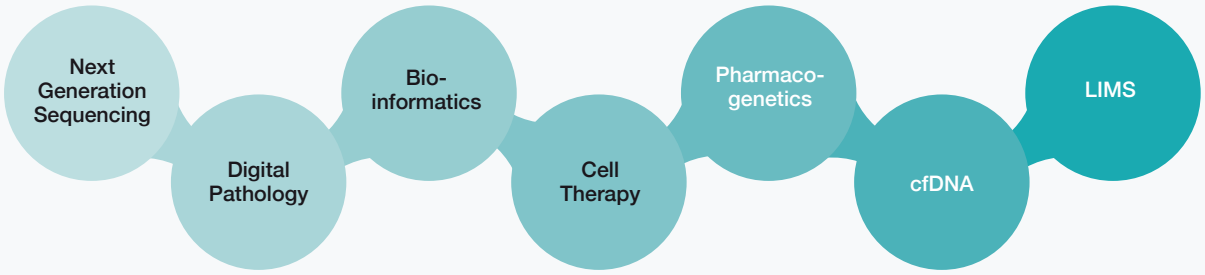
As scientific progress accelerates, urgent change is required to realise the full benefits of laboratory medicine, both now and in the future. This encompasses investments in both required infrastructure and the professionals operating within the laboratory environment. While the Irish laboratory medicine workforce is excellently trained to offer the current service, sufficient quantities of highly and appropriately trained staff are required to implement and integrate new best practice technologies, which are technically and scientifically demanding. This spans all laboratory disciplines, and without such developments, many specimens will continue to be outsourced, resulting in continued service fragmentation and unnecessarily prolonged turnaround times. A core principle of any such investments should be to ensure equitable access to services nationwide.

Laboratory medicine's foundational role in patient care hinges on the provision of a highly skilled workforce, modern infrastructure, advanced equipment, and seamless information technology and data integration. However, in a nationwide survey used to enhance our understanding of current practice, 68.9% of laboratories reported their current staffing complement as inappropriate for their department's workflow. Moreover, 61.3% of laboratories reported an inability to meet local and/or national turnaround times. Inappropriate IT/automation (90%), staffing (86.7%), and space (43.3%) were identified as the three greatest challenges faced by laboratories presently.

Throughout this review process, it was clear that many recruitment and educational difficulties exist within the health service, particularly in key disciplines. Given the ongoing technological enhancements in diagnostic testing, training, education, and professional development of laboratory staff will be key to the effective development of laboratory medicine services. With current and anticipated future international recruitment difficulties, investing in staff training and development may create a more promising career pathway that attracts and retains staff. The approach adopted should seek to maximise the scope of practice within each individual discipline relevant to their qualifications, training, and experience whilst developing career opportunities that allow for enhanced inter-professional training (where appropriate) and service collaboration. It is important to note that this approach should appropriately value individual qualifications and career pathways.

The advent of advanced practice and higher specialist roles for scientists should be seen as an opportunity to develop and strengthen the laboratory medicine workforce. Specialist training should aim to provide individuals with the skills and competencies required to be eligible for independent practice, where appropriate and within a defined scope. Such training should aim to bring scientists from all professions beyond advanced practice and towards autonomous practice. To realise this, a national workforce planning exercise is necessary. This should look to establish current and future need for the different professions, informing programme intakes to ensure the number of trainees is aligned with service requirements.

As described, technological and scientific strides hold immense potential for advancing laboratory medicine in Ireland. Embracing these innovations is not only crucial for refining current techniques but also for meeting future demand. For this reason, it is essential that laboratories keep pace. Seven interrelated technologies and scientific practices were identified during this process as critical for Irish laboratories to deliver a best-practice service. They are described in greater detail in *Section 3* and are as follows:



The current funding model for laboratory medicine in Ireland is based on historical costs, including a hospital's annual financial allocation, some of which comes through the DRG system and the rest from block grants for services. Despite being operational, this model is not optimal, lacking a ring-fenced budget for diagnostic clinical laboratory services. Consideration must be given to alternative ring-fenced models to enable the appropriate development and maintenance of services, especially concerning the significant volumes of community testing overseen by acute hospital facilities. Additionally, due consideration must be given to the overarching operating model employed as the HSE implements the HSE Health Regions. Moving towards a hub-and-node model, with a cooperative approach, may present an opportunity for enhanced collaboration and efficiency across laboratories.

Summary of Recommendations

Key Strategic Areas

Innovation, Change, and Reform

Due to changes in population health and rising levels of chronic disease, it is necessary that a networked, integrated, and agile laboratory service exists to support emerging healthcare needs. Laboratory medicine must be integral to the initial planning stages of service developments and reform across primary care, community, and acute services. This will be reliant on the adoption of innovative technology and advances in scientific practice that can significantly improve service delivery. They are viewed as essential to improving the accuracy and reliability of the techniques and processes currently employed, as well as being vital in meeting future demand. For this reason, Ireland must keep pace with new developments in the practice of laboratory medicine. This should be underpinned by appropriate infrastructures and reimbursement models, tailored to the needs of the service.

Workforce

In developing a workforce plan we need to acknowledge the global shortage of healthcare professionals and the need to develop a workforce in the context of an ethical and sustainable approach. For the future development of laboratory services, an approach needs to be developed and implemented that seeks to strategically align the range of scientific laboratory staff and support staff relevant to clinical service needs and the implementation of evolving technologies. This should be mindful of their differing skills, qualifications, and experience. The approach needs to be underpinned by clear recruitment (undergraduate/postgraduate), training, and on-going professional development systems. It is recognised that implementing these measures will take some time, and resultantly a series of more urgent actions should be considered to maintain services amid the current healthcare landscape. Furthermore, the approach should be cognisant of the need for a potential 24-hour service together with on-call requirements.

Digitalisation

A robust and modern health service must be underpinned by a digitally mature laboratory service. Central to this is an advanced laboratory information management system (LIMS) that facilitates the acquisition, management, sharing, and interpretation of pathology information in a digital environment. Laboratories cannot function effectively or efficiently without such systems and this requirement is becoming more prevalent as laboratory medicine evolves at pace with the introduction of more complex testing. Implementation of such technologies is reliant on investments into the hardware, power, and IT specifications to stand up the services. Furthermore, the creation of a digitally mature laboratory environment opens the health service to the prospect of other futuristic technologies, including machine learning and artificial intelligence.

Education and Training

Continuing advancements in laboratory medicine mean that both now and in the future education and professional development of laboratory staff is key to developing an effective laboratory service. The approach to the training, development, and career progression for all laboratory staff should be based on current best practice. Ideally, it should seek to maximise the scope of practice within each discipline relevant to their qualifications, legislation, training, and experience whilst creating opportunities that allow for enhanced inter-professional training and service collaboration. Optimising the potential of the staff will not only maximise the contribution of laboratory services to the wider health system, but it may also address scientific aspirations and enhance staff retention and return on investment.

Infrastructure and Equipment

In order to accommodate the expanded remit and developing functions of the laboratory, appropriate working environments are required. This includes the provision of appropriate space with the incorporation of fallow capacity to incorporate new technologies and service developments. Where necessary and appropriate, older and unsuitable facilities should be replaced by new infrastructure, and in doing so, consideration must be given to its strategic location with the hospital.

Summary of Key Thematic Considerations

Immediate Measures to Maintain Services Subject to Review

1) Investment into order communication systems should be prioritised to ensure optimal returns from investments into automation and track systems. Such investments can result in significant administrative savings in both the laboratory and medical record departments, whilst also enhancing patient safety.
2) The National Working Group recommends the expansion of medical laboratory aide (MLA) numbers and roles, and the development of career structures. A focus should be placed on recruiting those with the necessary education and credentialling required to take on numerous routine and manual tasks, freeing up scientists for other activities.
3) Despite the benefits of automation, across the entire spectrum there is an immediate need for additional appropriately qualified staff to undertake analytical tasks.
4) Engagement with CORU and the Department of Health is required to review the registration requirements for a changing workforce.
5) In the absence of voice recognition and allied services, there is a requirement for a range of administration support which will free up the time of both MLAs and scientific staff to conduct more pre-analytical and analytical tasks.
6) An immediate evaluation of laboratory ICT systems is required. The Group recommends that a feasibility project is undertaken urgently, with a commitment to implementing an effective inter-laboratory referral system. This will reduce staff time involved in referrals, decrease transcription errors, and improve patient service through decreased turnaround times.
7) Opportunities to leverage automation within the laboratory environment should be explored without delay. Reviews of optimal on-site service should be undertaken, and if additional automation is cost-effective and clinically appropriate, such projects should be prioritised.

Innovation, Change, and Reform

1) As new laboratory-based technologies are implemented in Ireland, consideration must be given to providing a robust regulatory environment to ensure the quality, safety, and efficacy of technologies used. All laboratory services must have quality management processes based on the relevant ISO standard.
2) Appropriate provision of testing currently outsourced should be adopted where inherent capacity is available. Repatriation of novel testing should be underpinned by structured training, certification, and registration of all scientific disciplines involved.
3) A formal working relationship with laboratory services should be established with national programmes such as the National Office for Genetics and Genomics, the National Screening Service, and other clinical and strategic programmes.
4) Given the rapidity of change in laboratory medicine, healthcare delivery, and technology, this review should be ideally updated within five years of publication.
5) A strategy needs to be developed to ensure that near-patient testing is provided with appropriate clinical governance, quality management and IT connectivity both in hospitals and the community.

Workforce

1) A national laboratory strategic workforce plan should be developed to support not only the recruitment of laboratory staff, but also the education, career development, retention, credentialling, and regulation of the current and future workforce.
2) For the future development of laboratory services, the health service should develop and implement an approach that seeks to strategically align the range of scientific laboratory staff (and their differing skills and qualifications) relevant to the clinical service needs and the implementation of evolving technologies.
3) Investment is required to develop and implement the advanced practice workforce underpinned by defined role and responsibilities.
4) The role of clinical scientists should be clearly defined and recognised within the health service.

Digitalisation

1) Based on the feedback received from the nationwide survey conducted, it is believed that the HSE should prioritise the implementation of electronic ordering, reporting, and transfer of results. This will significantly reduce the administration burden currently placed on MLAs and scientists, thus freeing up valuable time to focus on pre-analytical and analytical work.
2) To facilitate the adoption of digital pathology into mainstream practice, the HSE should look to create a policy and framework to ensure its safe implementation, as well as developing a national approach to procurement of the digital pathology infrastructure.

Education and Training

1) An integrated system for the training, education, and career advancement of laboratory staff is required. The adopted approach should seek to maximise the scope of practice within each scientific discipline relevant to their qualifications, training, and experience whilst developing career opportunities that allow for enhanced inter-professional training (where appropriate) and service collaboration.
2) Training programmes for all scientific professionals must be formalised and supported by the health service, with appropriate regulation and accreditation. Support requirements, for example, should include programme supervision, dedicated training time, appraisal processes, equipment and training space, portfolios, CPD, rotational experience, and the provision of a regional/national competitive selection process with defined criteria for appointment.
3) Dedicated graduate/postgraduate entry-level training programmes, as appropriate, should be developed for all scientific disciplines, allowing individuals with relevant degrees to enter into the respective professions under structured and regulated manner with appropriate training. The requirements should be tailored to the needs of the profession.
4) Advanced practice pathways, in accordance with the *HSCP Advanced Practice Framework*, must be developed through the implementation of a structured training programme tailored to the needs of the respective scientific professions.
5) Higher scientific training programmes should be developed to provide scientists with the skills and competencies required to be eligible for independent practice where appropriate and within scope of practice. The training is aimed to bring scientists from all professions beyond advanced practice and towards autonomous practice.
6) Implementation of specific pathways for training and development of scientists in specialist services, which may comprise a single national laboratory should be prioritised. This may require collaboration with other jurisdictions and laboratories with specific expertise, as well as support of secondments.

Infrastructure and Equipment

1) To accommodate the expanding remit and functions of the medical laboratory, appropriate working conditions must be provided with fallow capacity to incorporate new technologies and service developments. Where necessary, older, and unsuitable facilities should be replaced by new infrastructure and in doing so consideration must be given to its strategic location within the hospital. Current and future innovations should be deployed in a more agile manner to improve patient care where applicable, including mainstreaming technologies.

Introduction

Health Service Executive

In Ireland, health and personal social services are delivered by the Health Service Executive (HSE) through a series of hospitals (HSE and voluntary), local health offices, health centres, and clinics at community level. Health services can be broadly defined as those concerned with the promotion of good health, prevention of illness, and the diagnosis and treatment of illness. They are delivered through numerous National Service Delivery Divisions, including:

- Acute hospitals.
- Social care.
- Mental health.
- Primary care.
- Health and wellbeing.
- National ambulance service.

Acute services are currently delivered via seven Hospital Groups (HGs); networks of hospitals working in tandem to provide acute care for patients. Health and social care in the community by contrast is provided via nine Community Health Organisations (CHOs). They do not align with the HGs in terms of geographies, management, clinical oversight, or budgets.

Non-aligned structures for hospital and care in the community does not support the delivery of integrated care. It was announced in 2019 that six new HSE Health Regions (HRs) are to be implemented. They aim to facilitate comprehensive integrated, person-led, community-first health, and social care through alignment of acute and community-based services. These Regions are to be introduced over the course of 2023 and to be operational by 2024.

Sláintecare

In 2016, the Dáil established the Committee on the Future of Healthcare with the goal of achieving a cross-party agreement on the future of the health service. Their aim was to create a ten-year plan for reform, setting out the committee's agreed vision and strategic plan. It focuses on delivering a safe, quality health and social care service that meets the needs of the growing population. It also strives to provide a single-tier health service where patients are treated solely based on health need, with individuals receiving the right care, in the right place, at the right time. Furthermore, it aims to create an environment that attracts and trains the very best health professionals, managers, and staff.

Review to Inform the Strategic Direction of Laboratory Medicine

As the HSE undergoes extensive reform, it is imperative that an agile clinical diagnostic laboratory service exists to support the emerging needs of both the population and healthcare system. In March 2022, a National Working Group was established to *Inform the Strategic Direction of Laboratory Medicine*. The overarching purpose of the group was to undertake a review to inform a strategic, integrated approach to developing laboratory medicine services, which will in turn enable and enhance healthcare reform.

The review will focus on four key areas seen as critical to inform the development of a strategic approach:

1. Map out current services and structures with a focus on national services to identify and understand the current practice in pathology departments.
2. Consider education and credentialing pathways to support professional development of laboratory staff with a broad-based educational approach that is reflective of their area of competence and expertise and aligned to evolving best practice standards and service requirements.
3. Review of scientific and technologically enabled advances in laboratory medicine.
4. Consider relevant international models of care and lessons learned to inform future direction.

Role of Pathology and Laboratory Medicine Services in Healthcare

In recent years, and particularly during the SAR-CoV-2 pandemic, there has been an increased recognition of the importance of diagnostic testing in healthcare in addition to the need for universal health coverage.

Role of Pathology and Laboratory Medicine Services in Healthcare

Clinical laboratory diagnostics are an essential component of holistic care and integral component of any healthcare system. It provides insightful data and, in many cases, diagnosis for conditions that cannot be distinguished clinically. Moreover, in the management of chronic conditions, access to diagnostics is required for the monitoring and adjustment of therapy. For example, Type 1 and 2 diabetes mellitus relies on the provision of tests such as blood glucose and HbA1c to both diagnose and inform ongoing acute/chronic management. In complex conditions, such as breast cancer, effective treatment would not be possible without accurate histological interpretation of tissue samples which facilitate targeted therapy and neo-adjuvant treatments.

From the perspective of infectious diseases, clinical laboratory diagnostics allows the accurate detection of disease, surveillance of variants and new emerging threats, as well as monitoring treatment responses and resistance. The above list is by no means exhaustive, and as we move to the future (e.g., with practices such as precision medicine gradually becoming the norm), the importance of quality clinical laboratory diagnostics will only increase.

Diagnostics as Part of Resource Stewardship

Although many clinical conditions can be diagnosed from thorough history and examination, this is not universal. In many situations, the absence of appropriate laboratory investigations can result in wasteful or inefficient treatment at best, whilst being harmful to patients at worst. Examples include the referral of primary care patients to Cardiology when heart failure is suspected. The introduction of B-type natriuretic peptide (BNP) testing has revolutionised this referral pathway, with higher rates of appropriate diagnosis. A further example involves the use of faecal calprotectin to appropriately triage patients with gastrointestinal symptoms, reducing referral for endoscopy.

Diagnostics as Part of a Healthcare System

Functional healthcare systems rely on overlapping and intersecting networks of providers, facilities, programmes, and data. Diagnostic testing is one of such networks. The accurate and timely provision of testing guidance, as well as test results with appropriate interpretative comments and clinical advice is essential in managing patients in a timely/efficient manner. Moreover, it facilitates patients being directed to the appropriate level of care, in the correct facility, in addition to informing and supporting referrals/specialist consultations. It is, therefore, vital that users of the healthcare service can trust in the results being delivered when so many key decision points are based on the data provided.

It is imperative that the use of clinical diagnostic laboratories is not seen purely as a transactional commodity delivering results. Instead, they should be viewed as an integral component of value-based care providing clinical insights. Examples of proposed additional roles include population health, chronic disease management, and disease surveillance, to name a few. Clinical guidelines can improve the clinical appropriateness of testing, addressing both overutilisation and underutilisation of tests, to bring the value of appropriate testing to patient care.

Diagnostic Testing in Public Health and Epidemiology

Clinical laboratory diagnostic testing provides much of the data used for epidemiology and disease surveillance, as well as the diagnosis and management of communicable diseases of public interest (e.g., tuberculosis, SARS-Cov-2). Whilst some of such testing occurs in reference laboratories including the National Virus Reference Laboratory (NVRL), the majority is generated through routine testing in acute hospital laboratories. With respect to microbiology, such testing is essential for monitoring antimicrobial drug resistance which is in itself a global health concern. Furthermore, the testing data generates much of the data used to populate registries, such as cancer registries which are vital for monitoring disease epidemiology.

Diagnostic Testing as Part of Research

In addition to their role in clinical practice, clinical diagnostic laboratories are integral to numerous forms of clinical and translational research. They can be used to evaluate the effectiveness of new medications, monitor for safety and potential side effects, in addition to establishing safe/therapeutic drug levels. Furthermore, clinical diagnostic laboratories are also utilised to evaluate the effectiveness of new therapies whilst also monitoring the ongoing efficacy of prior research findings.

Quality Assurance in Clinical Diagnostic Laboratories

Laboratory medicine has played a leading role internationally in the incorporation of quality assurance and quality improvement in healthcare. External accreditation of clinical diagnostic laboratories has been in place for over 20 years in Irish hospitals and such expertise in QA is underutilised by the wider healthcare system. Examples of transferable skills include quality management, document control, process risk assessment/management, internal/external quality control, and system analysis for non-conformances/ incident investigations. From a national perspective the Faculty of Pathology has overseen the successful implementation of the National Histopathology Quality Improvement Programme (RCPI, 2022) which since 2009 has been providing national quality metrics on the performance of histopathology laboratories, the first country to provide this information at a national population-based level. Irish External Quality Assessment Scheme (IEQAS) also provides a valuable service for several areas of the laboratory.

Diagnostics as Part of Near-Patient Testing

Near-Patient Testing (NPT) aims to improve patient outcomes through provision of a laboratory medicine service by healthcare professionals using small analytical devices provided near to the patient rather than from a clinical laboratory. Demand for NPT services has grown considerably since the first national guidelines were issued in 2007. It is envisioned that demand will continue to grow in this expanding area of laboratory medicine due to technological advancements, the convenience of fast turnaround times and the lack of need for specimen transport.

In 2021, the updated **Irish National Near-Patient Testing Guidelines** were issued in conjunction with all major stakeholders. The guidelines emphasise strongly the need for robust clinical and managerial governance to comply with relevant national and international regulations and accreditation standards. Of particular relevance are the **In-vitro Diagnostic Medical Device Regulation 2017/746/EU (IVDR)** and ISO 15189:2022 Medical Laboratories – Requirements for quality and competence.

The essential requirements of the IVDR aim to ensure that IVDs do not compromise the health and safety of patients and users, and are designed to achieve the performance specified by the manufacturer for its intended purpose. The rapidity of obtaining a result can increase clinical effectiveness and contribute to improved outcomes for patients, but it is essential that the result provided by the device is accurate, reliable, and visible in the patient's health record. Therefore, it is imperative that NPT services in hospitals and in the community retain close links to local, centralised pathology services utilising the expertise of laboratory professionals.

NPT departments are now well established in acute hospital laboratories nationwide, providing governance and quality management of services. However, Sláintecare initiatives to expand primary care will undoubtedly create extra demand for community NPT projects to deliver diagnostics outside of the hospital environment. Laboratory expertise will be essential for many aspects of community NPT including:

- Clinical governance.
- Quality management.
- Choice and suitability of test/platform.
- Training and competency assessment.
- Pre-analytical variables.
- Proper analytical techniques.
- External quality assurance.
- Internal quality control.
- Traceability.
- IT connectivity.
- Reporting adverse incidents to the HPRA.

Many respondents to the survey conducted to inform this review noted lack of resources for NPT as an impediment to current service provision. Future initiatives in the community setting will result in further pressure on these resources. It is important that requests for NPT services are considered in relation to the overall healthcare cost/benefit analysis rather than viewed solely as a laboratory expense, as NPT has the potential to facilitate streamlined patient pathways and improved outcomes.

Promoting the Role of the Laboratory

As described above, clinical laboratory medicine plays a vital multi-dimensional role within the healthcare sector. Data from the UK demonstrates that 95% of clinical pathways require access to timely medical laboratory testing, with an average of 14 tests per annum performed per person in England and Wales (RCPath, 2022). Continuing work to collect Irish data is needed. Their role within primary care must also not be understated – in the UK, GPs receive 900,000 electronic pathology reports per million population per annum.

Laboratory medicine underpins effective and safe patient care and is reliant on a highly trained workforce, effective infrastructure, leveraging the benefits of modern equipment and automation, as well as information technology and data integration. Quality assurance of services should include appropriate accreditation, registration, and regulation of all professional staff and a culture of audit and quality improvement.

In order to maximise the value of testing, clinical advice may be sought both before testing and for interpretation of results. This allows optimal use of resources and can help prevent over-ordering and unnecessary repetition of tests. Less frequently recognised is underutilisation of tests, where patients' diagnosis or treatment is impeded because of delayed or inappropriate testing. For this reason, both medical and scientific staff are frequently involved in the development of clinical pathways, to advise on optimal testing at the respective stages of the pathway. Furthermore, within pathways, advice regarding the significance of results, particularly those which are borderline, is crucial to prevent inappropriate investigations or treatment, or a delay in the diagnostic process. This is a key contributor to patient safety.

Provision of key tests with appropriate turnaround times can add considerable value to the healthcare system. For example, having rapid turnaround time for agreed tests within the emergency department facilitates early diagnosis and appropriate intervention, which in turn supports patient flow through the department. The ability to provide such services is however reliant on appropriately staffed laboratories, rapid delivery of specimens to the laboratory (air-tube or by porter), identification of priority specimens, laboratory automation where appropriate, and IT infrastructure (such as electronic requesting and reporting of results). The benefits of rapid testing also extend to other clinical areas including wards, critical care, infusion suites, and chemotherapy day wards. It can help speed up decision making which can allow earlier discharges, rapid turnover of beds, and reduced trolley times.

From a community perspective, access to clinical laboratory diagnostics is fundamental to allowing general practitioners to manage patients in the community where possible. In Wales, they target a 95% turnaround rate for an agreed suite of tests to be processed and reported by hospital laboratories by the end of the day, allowing patients to be managed in the community where safe (Cancer Waiting Targets – A guide for Wales, 2022). Again, such targets are reliant on robust infrastructure including appropriately staffed acute laboratories, adequate transportation, and functional IT/Automation.

Clinical diagnostic laboratory services have the potential to reduce demand for invasive and/or uncomfortable tests. For example, appropriate use of faecal calprotectin testing in the UK (as advised by clinical guidelines) has not only reduced patient referrals to specialist gastroenterology clinics, but also demand for colonoscopy (Hesham Khalil). Given the current challenges associated with waiting lists post COVID, such investment and interventions may prove useful in improving waiting times and reducing demand.

Investment in best-in-practice laboratory testing can improve patient outcomes. For example, advanced cross-matching techniques have improved the survival of kidney transplants, helping patients remain off dialysis for longer, thus reducing the need for dialysis stations. Timely diagnosis of leukaemia and bleeding disorders leads to targeted treatment. Haemorrhagic emergencies such as postpartum haemorrhage are life threatening and require an active and efficient transfusion laboratory service. Other examples of advanced techniques that can be employed to improve patient outcomes are discussed in *Section 3*, such as the role for cell free DNA in prenatal testing.

In order for the healthcare system to benefit from the value that laboratory medicine can bring, laboratories need appropriate staffing with the skills to develop and offer high-quality diagnostic testing with optimised turn-around times. Advice to assist with decisions in relation to choice of tests, in addition to interpretation of results for individual patients, at multi-disciplinary meetings, as well as at the level of protocol design helps ensure that patients get the right test, at the right time and that the correct result is received, understood, and acted on. Laboratory medicine should not be viewed as a cost generator, rather than a service that adds value and facilitates overall cost containment.

Need for Change

Over recent years, it is believed that there has been a significant lag phase in the development, funding, and implementation of new technologies that will allow Irish patients to benefit from scientific and medical advances in a timely fashion. As scientific developments now advance at rapid pace, urgent change is required to realise the full benefits of laboratory medicine both now and in the future. By example, there are areas such as transplant immunology where more than 95% of testing is achieved using techniques that were not routine circa 10 to 15 years ago.

Whilst the Irish laboratory medicine scientific workforce is excellently trained to offer the current service, it requires significant development of advanced practice to allow the implementation and integration of new technologies which are technically and scientifically demanding. This spans all laboratory disciplines and in the absence of such developments, many specimens will continue to be sent abroad, further fragmenting the services with unnecessarily prolonged turnaround times. Repatriation of these services requires among other measures, development of a suitably skilled, agile scientific workforce, together with structured training, appropriate certification and registration of all scientific disciplines involved. In addition to a skills gap, many tests are referred abroad purely due to capacity issues. Repatriation of such services does not require significant upskilling, or advanced practice, but rather development of current capacity. This too will improve turnaround times, facilitate multi-disciplinary team (MDT) input, and ensure patients benefit from currently available advances in laboratory medicine.

All developments in healthcare require critical evaluation to assess real clinical utility and impact on clinical pathways. Such evaluation should be multi-professional, including advanced scientific practitioners contributing to an MDT. Senior scientific personnel can make an invaluable contribution to the MDT, horizon scanning current and soon-to-be available scientific options, desktop and wet method and assay evaluations, as well as validation and implementation of new methods. Such expert scientific input is essential to allow the MDT to choose new tests which impact management, are likely to stand the test of time, and to determine which existing tests may be replaced. Laboratory scientists are adept at implementing and consolidating change. Fulfilling these advanced scientific roles requires change in the system.

Existing laboratory medicine services are key to providing modern healthcare services. It is therefore essential that in addition to promoting the development of laboratory practice, investment should be provided to ensure equitable access of services across the nation. Developing Irish services for advanced diagnostics will however offer benefits to patients across the clinical spectrum. Some examples of opportunities, which will be supported by the development of advanced laboratory practice include:

- **Chronic disease management** is a growing challenge, with significant resources required as the population ages. Significant improvements have been made in developing integrated hubs for chronic disease management in line with the Sláintecare vision. Thirty integrated hubs for chronic disease management are being established, each aligned with an acute hospital, with the remit of supporting chronic disease management in the community. This presents a welcome opportunity to develop and bring laboratory medicine closer to the patient, in an accredited, quality-assured manner. To support such developments, advanced laboratory practice will be required in addition to the other necessary infrastructures.
- **Disease prevention:** Laboratory medicine is integral to the prevention of disease – screening plays an important role ranging from neonatal bloodspot screening to cancer screening at a population level.
- **Effective use of medications** frequently relies on laboratory medicine. Laboratory medicine plays an essential role in many circumstances prior to prescription of medications, monitoring response, dosage, or toxicity as well as selecting and prioritising therapeutic options.
- **Monitoring of novel anticoagulants:** Widespread use of novel anti-coagulants, which are not straightforward to reverse causes significant risks if emergency surgery is required. It is necessary to ensure appropriate access to new assays which monitor bleeding risk and roll out of validated assays for 24/7 use in all sites performing major emergency surgery.
- **Supporting the development of near-patient testing** in an accredited, high-quality manner offers several benefits to patients, while poor quality near-patient testing is a clinical risk. Implementation of the Sláintecare vision will be assisted by high-quality laboratory-supported near-patient testing. This will require development of senior scientists supporting such programmes, which requires high-level scientific, educational, and management skills.
- **Maternity care** can be improved with techniques using flow cytometry and detection of fetal DNA or cells in maternal blood to allow non-invasive fetal screening. Similar technology can be used to identify a rhesus negative fetus of a rhesus negative mother, as well as monitoring for feto-maternal haemorrhage to inform use of anti-D and diagnose alloimmune cytopenias. Such techniques are technically challenging, have limitations and require careful quality control.
- **Cancer care** has been greatly enhanced by the development of companion diagnostics – identifying patients likely to respond to novel biological therapies. Care can be further enhanced by developing and expanding molecular analysis of tumours, and the use of tumour derived cell-free DNA can facilitate liquid biopsies, allowing diagnosis in people who are not fit for invasive procedures. Cell-free DNA can play an important role in monitoring treatment in several cancers (e.g., MRD). However, for Irish patients to benefit from these advances, timely cell-free DNA analysis will be required, and must be delivered in an expert, quality assured manner. Given the rapid pace of advances in this area, advanced practice both in molecular biology and bioinformatic skills will be required.
- **Irish solid organ transplant** outcomes exceed OECD and EU averages. Laboratory medicine is one of many factors contributing to such outcomes, with the existing workforce continually developing and adapting the services. However, additional diagnostics including the use of donor derived cell-free DNA to monitor graft function, gene profiling to assess immune responsiveness as well as cellular immunology techniques to balance infection and rejection risks are not yet available. Implementing these advances will require enhanced expertise in genomics and cellular immunology.

- **ongenital and rare diseases:** Access to appropriate gene panel and exome sequencing is required to support diagnoses of congenital and rare diseases. For example, rapid exome sequencing in children admitted to neonatal intensive care units has been shown to generate actionable findings in 40% of children, and changes management in 18% of children (Olde Keizer, 2023). Such an approach assists with the rapid implementation of appropriate management which can be life changing. It can reduce the need for imaging and other diagnostic procedures, as well as potentially identifying information which can assist families with future reproductive decisions. However, in order for such technologies to be meaningful in clinical management, appropriate TATs are required.
- **Biochemical testing** remains critical to identify several rare or congenital disorders, or to confirm a genetic variant as being pathological. Rapid metabolomics methods are being developed which can provide these answers in a timely manner.

Immediate Measures Required Subject to Review

The Clinical Diagnostic Laboratory Service is currently under unprecedented pressure, with vacancies at a level that threatens existing services and the ability to provide on-call services. This staffing shortage comes at a time of increased demand for services in volume, complexity, and with the expectation of a 24/7 service in the context of key priorities. Resultantly, a review of service hours provided should be considered. Recruitment is highly challenging for a multitude of reasons, and the resultant supply of staff cannot keep pace with demand. It is in the interests of patients to ensure that available staff are appropriately deployed. The group recommended the following supports be considered.

1) Order Communications

Many laboratories, of all sizes and complexity, have no order communication systems. Clinicians, within hospitals and in primary care, must handwrite requests which must then be manually entered into laboratory systems, with attendant potential for transcription error. Reports are printed and returned to clinical areas, frequently being transcribed again into clinical systems. Investment in automation and track systems cannot yield optimal returns unless this matter is addressed immediately. Investment in order communications can result in significant administrative staff savings in both the laboratory and medical records departments, whilst also enhancing patient safety.

2) Expanding Medical Laboratory Aide (MLA) Numbers and Roles

To maintain current service, it is necessary to increase the number of MLAs and expand their role. Additional MLAs that have the relevant education and credentialling are required to take on some routine and manual tasks from pre-analytics through to some analytic tasks. Currently, highly skilled scientists are undertaking tasks which do not require their level of training. This is inefficient, and at a time of critical manpower shortage, unsustainable. It must be recognised that a number of MLAs are indeed highly qualified with a science degree, or qualified laboratory scientists in other countries.

It is proposed to develop a career pathway for MLAs to allow them to develop additional skills and competencies to undertake certain aspects of tasks including running analysers and tracks, undertaking bench tasks and multiple manual tasks across all laboratory disciplines. Development of a career pathway could allow more effective deployment of scientific staff. In addition to development of a career structure, it is essential that adequate numbers of MLAs are appointed within laboratories, while maintaining an appropriate ratio of scientists to MLAs. At present in many laboratories, when a MLA takes leave, their duties are covered by a scientist. Given the current staffing crisis, this should be reviewed.

Development and enhancement of structured support roles to assist scientists working in our clinical diagnostic laboratories is essential. This will allow support grades to undertake the more repetitive tasks, freeing up the scientists to undertake more complex roles, research, and development for which they are trained. Maximising the potential of scientists is thought to be key in improving staff retention.

3) Adequate Clerical and Administrative Support

Many scientists and pathologists spend several hours per week undertaking administrative tasks. This is highly inefficient and prevents appropriate skills usage. It is essential that adequate administrative support staff are in place to support laboratory medicine services.

There is a need for a range of administration support who can undertake sample acceptance procedures (in the absence of an entirely integrated order comms system) and have the competence to type up histology and molecular reports. By enhancing the roles of administration staff, it will free up both lab aides and scientific staff to do more pre-analytical and analytical tasks. Technology such as voice recognition and template reporting must also be considered as an alternative means to free up medical and scientific time.

4) Enhanced ICT Support

Immediate evaluation of systems which may offer an effective system for interlaboratory referrals, both within Ireland and the UK where many outsourced samples are sent, should be explored immediately. Such a project in the UK has been highly beneficial, decreasing staff time involved in referrals, reducing transcription error, and most importantly improving the service to patients by decreasing turnaround times for referral tests.

Consideration should be given to undertaking a feasibility project, with a commitment to implement. Existing laboratory information systems should consider incorporating the individual health identifier to facilitate merging of records in the future.

5) Enhanced Automation

Opportunities to leverage automation should be explored. While many laboratories have undertaken laboratory modernisation projects, some laboratories have limited automation. A review of optimal on-site service should be undertaken, and if additional automation is cost-effective and clinically appropriate, such projects should be prioritised.

Section 1.0

To map out current services and structures with a focus on national services to identify and understand the current practice in pathology departments.

Section Overview

Introduction

In order to inform the strategic direction of laboratory medicine, we must first understand current service delivery in Ireland. This section focuses on defining the 'as-is' by mapping the current landscape of personnel, specialties and governance structures that exist within acute hospital laboratories.

Laboratory services in Ireland have developed locally and organically, primarily driven by service needs and technological/scientific advances. In 2011, the National Clinical Programme for Pathology was established as a joint initiative between the Health Service Executive (HSE), the Royal College of Physicians of Ireland (RCPI), and Clinical Design and Innovation. This programme reports to the Office of the Chief Clinical Officer (CCO), along with 32 other national programmes. The Office of the CCO was established in 2018 to "further develop clinical leadership across the healthcare system and ensure that it is central to the design and implementation of policy" (HSE, 2019).

It is important to note that this review recognises prior reports and recommendations focussed on the delivery of laboratory services in Ireland. The 2007 Teamwork Report (Teamwork Management Services Limited, 2007) recommended consolidation of 'cold' work to achieve economies of scale at large centralised testing centres. This recommendation was later reinforced by the Laboratory Modernisation Agreement published in 2011 (HSE, 2011) which again committed to consolidating services within the public sector by forming a 'hub and spoke' model. Despite these reports, consolidation remains variable and largely unimplemented and unrealised. However, one must note that in the interim, laboratory services have remained responsive to clinical need, expanding the range of analysis and routine hours of service.

Advances have occurred in all areas of medical and laboratory medicine, and coupled with an increased need for clinical interaction, have seen demands for laboratory services increase. Despite this, insufficient staff, space, and infrastructure are reported widely throughout the system and are hindering adequate service provision and development. This section, including the findings of the nationwide survey, represents a snapshot in time of what is a rapidly evolving group of specialties. It will form the basis and foundation for the various considerations discussed throughout this review to inform the strategic direction of laboratory medicine.

Methodology

In addition to consulting prior reviews, government publications, and data collected by various professional bodies/stakeholders, a nationwide questionnaire was used to enhance our understanding of current practice and fill deficits in knowledge. Laboratory managers in acute hospitals across the nation, were invited to participate in a survey over a 12-week period (commencing June 2022) in conjunction with their respective scientific leads, consultants, and clinical directors. Laboratories outside of acute hospitals are not included in this review. A total of 31 out of 42 laboratories submitted responses. Key areas of focus within the survey included staffing, vacancies, technologies used, and services provided.

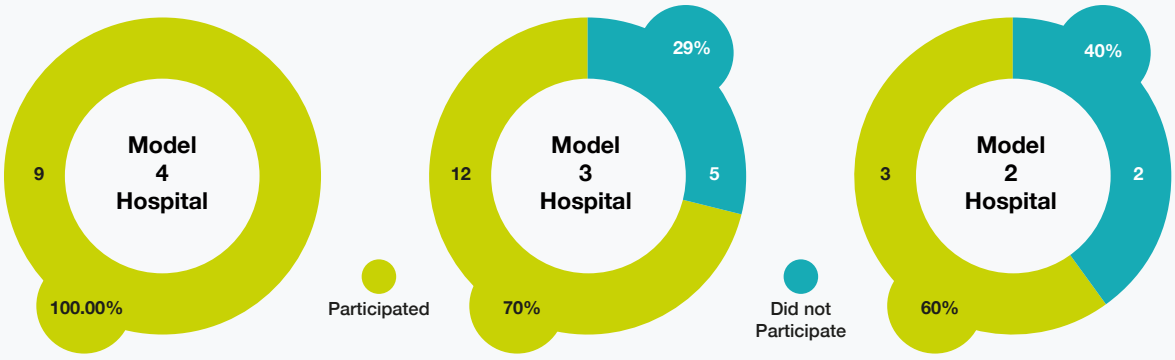


Figure 1: Hospital Model Participation Rates

Laboratory System Overview

The majority of Irish public medical laboratories are based in acute hospitals and provide a comprehensive range of services to both primary and secondary care. Services focus on the provision of diagnostic and consultative services and include blood transfusion, haematology, clinical biochemistry, histopathology, immunology, microbiology, as well as reference services. Traditionally, most hospitals provide 24/7 services for clinical biochemistry, haematology, and blood transfusion, whilst immunology, histopathology, and microbiology are provided at a large number of hospitals and are typically not 24/7 but will provide specific tests and investigations outside of normal hours. Specialised reference services are provided by a small number of centres that developed largely in an ad hoc fashion based on the distribution of expertise. Figure 2 below shows the percentage of labs surveyed providing each of these services.

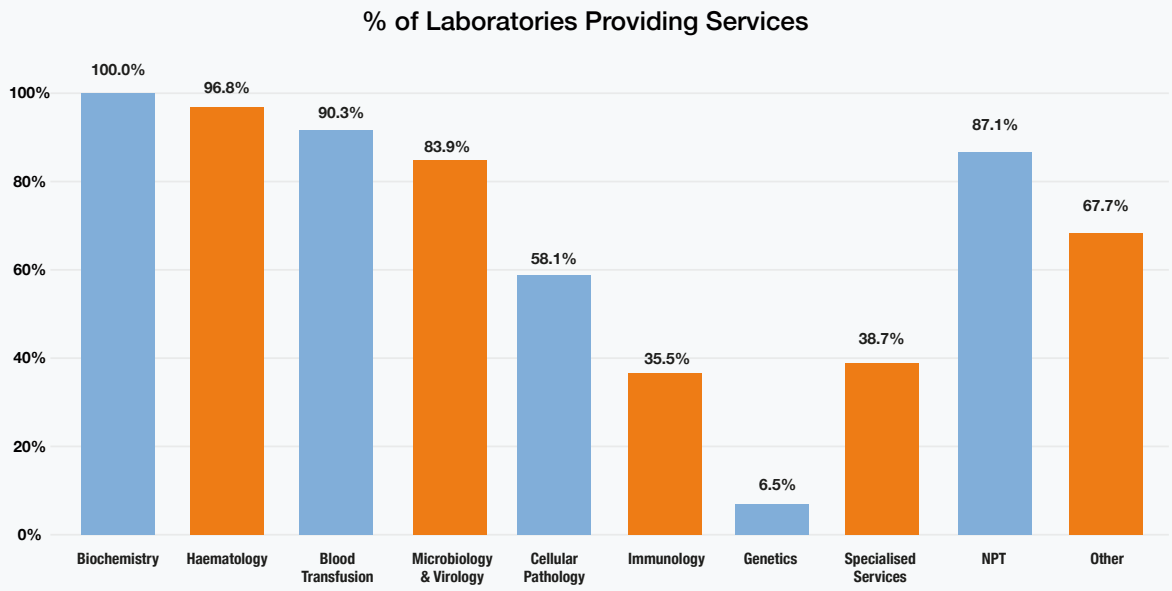


Figure 2: % of laboratories providing services

Whilst all Model 3 and 4 hospitals have on-site laboratories, this is not the case for Model 2 centres which frequently rely on larger centres. They provide outpatient and inpatient care for those patients deemed low-risk and who are unlikely to require resuscitation in the event of an arrest. Those deemed at risk of deterioration are typically cared for in Model 3 (General) and 4 (Tertiary) centres.

Acute hospital laboratories services are provided by medical scientists, clinical biochemists, clinical scientists, medically qualified pathologists, as well as MLAs and clerical staff. Laboratory scientists work collaboratively with clinician colleagues and consultants (medically qualified pathologists or consultant clinical biochemists) as appropriate for their respective disciplines.

Governance

Laboratory Structure

Governance structures in laboratories are complex and vary significantly depending on the size of the facility, services offered, and level of experience held within the laboratory. That said, there are general principles that apply, and the below diagram provides a high-level overview of the reporting structure typically employed in acute diagnostic laboratories.

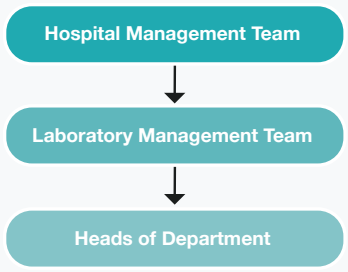


Figure 3: Sample laboratory structure

Of the three scientific professions the vast majority are medical scientists (circa 95% of scientific staff). Clinical biochemists work within clinical biochemistry (and its sub-specialties) and clinical scientists tend to perform specialised testing in their specific area of expertise. Currently in Ireland, medical scientists receive multidisciplinary education and clinical placements in all main specialties within the lab before specialising upon completion of their undergraduate training. Laboratory managers are drawn from the pool of medical scientist staff. This is in addition to other laboratory positions such as surveillance scientists and business, quality, and ICT managers, who are typically drawn from a variety of backgrounds (including the pool of current scientists).

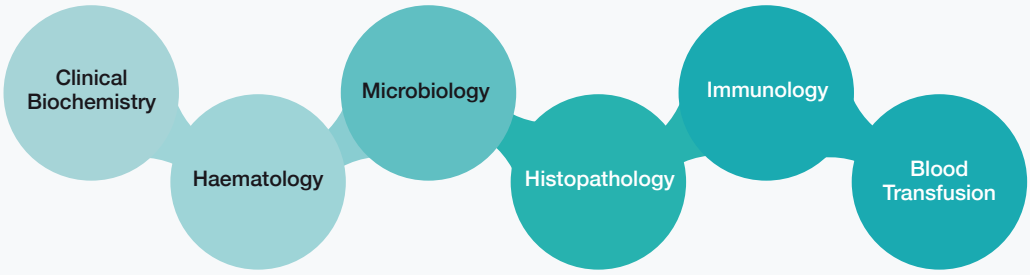
Clinical governance is provided by pathologists and consultant clinical biochemists. Pathologists are medical specialists that play a key role in governance and clinical leadership of laboratories. They advise clinical colleagues about appropriate testing (both at individual patient and guideline level) as well as advising about interpretation of results and subsequent patient management. Pathologists analyse and report specimens, as well as providing direct patient care as appropriate to the discipline. Clinical biochemistry laboratories are led by consultant clinical biochemists and/or consultant chemical pathologists. They are accountable for service quality, developments, and clinical governance.

The laboratory management team is multidisciplinary and plays a central role in providing leadership and setting the strategic direction of the laboratory to ensure the delivery of an effective, efficient, quality-assured, and patient-centred service.

Overview of Laboratories

Overview

Laboratories are divided into six key areas – clinical biochemistry, haematology, medical microbiology, histopathology, immunology and transfusion science – with each discipline contributing independently and interactively to patient care. Details of the main functions of each traditional specialty are provided below. Rapid technological and scientific advancements have seen further specialisation into other areas such as coagulation, cytology, endocrinology, histocompatibility and immunogenetics, immunohistochemistry, genetics, genomics, metabolic medicine, molecular diagnostics, near-patient testing, therapeutic drug monitoring, toxicology and virology among others. Supporting these scientific disciplines are teams with expertise in laboratory informatics and quality management systems. This list provides some insight into the breadth and depth of services and specialties within our clinical diagnostic laboratories and the complexities of considering the department of pathology and laboratory medicine as a single entity. Rapid technological advance and automated platforms have led to some workload consolidation, nevertheless, optimal patient care requires that scientists and pathologists have the in depth knowledge of these speciality areas and understand the limitations of the testing methods to provide advice on test utilisation and interpretation of results to guide clinical decisions.



Clinical Biochemistry

Clinical Biochemistry (also known as chemical pathology) involves the biochemical investigation of bodily fluids such as blood, urine, and cerebrospinal fluid. Through such investigations and the identification of where/how one's body chemistry has changed; it is possible to diagnose and monitor disease. Examples of conditions covered within the scope of chemical pathology are dyslipidaemia, diabetes, electrolyte/ nutritional disturbances, kidney function, liver disease and cardiac disease. Measurement of circulating proteins can indicate infective or inflammatory processes which may be more fully investigated elsewhere.

Haematology

Haematology is the specialty responsible for the diagnosis and management of a wide range of benign and malignant disorders of the blood and bone marrow in adults and children. This may include serious life-threatening illnesses including leukaemia, lymphoma, or myeloma, requiring urgent intervention. This specialty is also involved in the diagnosis and treatment of various forms of anaemia. Detailed examination of the distribution of white cell subtypes can assist in the diagnosis and monitoring of infective or inflammatory disorders.

Microbiology

Microbiology is a broad specialty encompassing laboratory, clinical and research aspects of infectious diseases, from 'diagnosis through to bedside'. It achieves this through a combination of traditional microscopy and culture methods in conjunction with novel diagnostic techniques such as molecular and proteomic techniques. It involves the identification of microorganisms, antimicrobial sensitivity testing, surveillance, and epidemiology. While improvements in technology have revolutionised this specialty with the advent of molecular methods much of traditional microbiology laboratory practice is dependent on the knowledge, skill, and competence of the scientist to recognise what is growing on the plate.

Histopathology

Diagnostic histopathology involves the gross and microscopic examination of tissue specimens to discover whether disease is present and what course of action should be taken. Specimens are typically collected in clinic or during an operation/procedure such as endoscopy, biopsy, or resections. Specimens gathered from post-mortem examinations are reviewed to assist in the identification of cause of death. These specimens must be processed through chemicals and wax in such a way as to maintain the 'real life' architecture of the tissue and stained with dyes to permit the examination of the tissue and its cellular components. A combination of scientific expertise along with histopathologic examination/interpretation by a medically qualified consultant histopathologist leads to the issuance of the report.

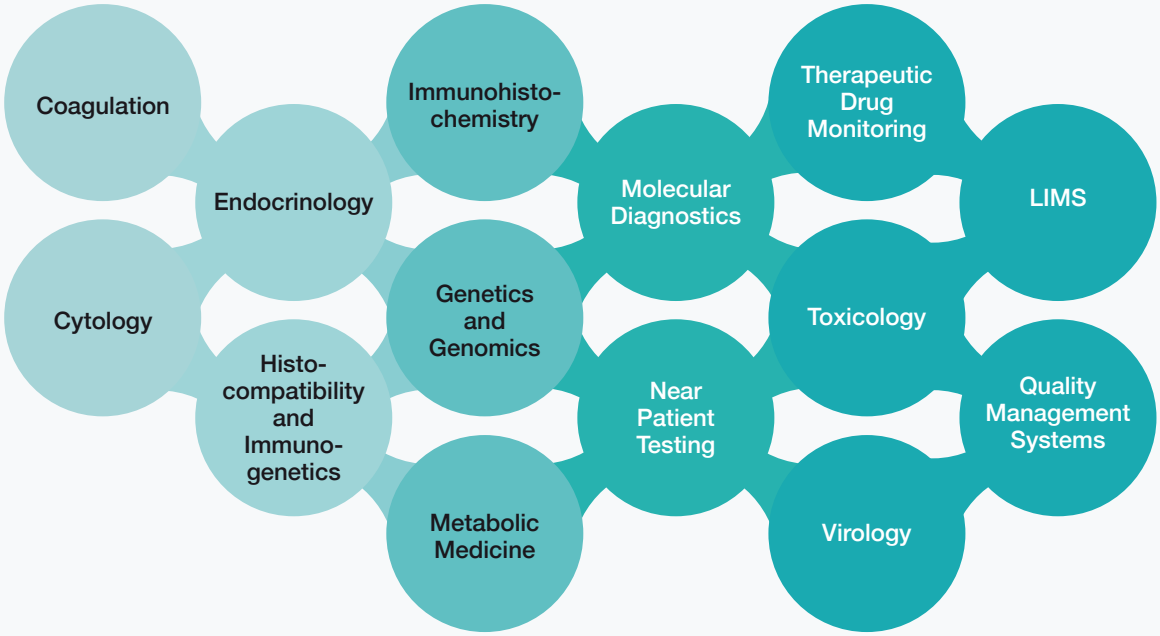
Immunology

Immunology is a combined clinical and laboratory discipline. Immunology is a branch of pathology concerned with the immune system and how it protects from, and contributes to, disease. It incorporates both the analysis of specimens as well as management of patients with immunological disorders. Core services are for those with allergic disorders, and patients with primary and, increasingly, cases of secondary immune deficiency. Examples of other more specialised areas including investigating those with vasculitis, complex autoimmune diseases and neuro-immunology.

Transfusion Science

Transfusion laboratories are responsible for compatibility testing and the issuing of compatible blood products to patients. It is an example of personalised medicine whereby a product is matched against a patient's antibody/antigen status, thus reducing the risk of a transfusion associated reaction. The team in a transfusion laboratory is critical for operating theatre function especially in the case of major haemorrhage and to the emergency department in cases of severe trauma where speed and accuracy is of the essence. This science plays a major role in antenatal care, preventing development of haemolytic disease of the newborn (rhesus disease). New technologies in this area involve in the collection and processing of haematopoietic stem cells for blood and bone marrow transplantation.

Subspecialties



Coagulation: Investigation of bleed and clotting disorders.

Cytology: Cytopathology specifically involves the examination of individual cells or clusters of cells from bodily tissues or fluids to determine a diagnosis. A common application of cytopathology is the "smear test" (gynaecological cytopathology), used to detect precancerous cervical lesions and allow earlier intervention.

Endocrinology: Investigation of endocrine disorders such as thyroid disease, adrenal disease, fertility issues in males and females.

Histocompatibility and Immunogenetics: Critical compatibility testing required for solid organ transplant.

Immunohistochemistry: Involves the identification of specific proteins in tissues to aid in diagnosis and sub classification of certain tumours. Can support provision of specific cancer therapies.

Genetics and Genomics: Examination of the DNA within cells to identify hereditary and other genetic disorders or the carrier status of an individual. Prenatal genetics can identify the presence of an abnormal number of chromosomes suggestive of conditions such as Edwards syndrome. Genomics involves the sequencing and analysis of genomes through uses of high throughput DNA sequencing and bioinformatics to assemble and analyse the function and structure of entire genomes

Metabolic Medicine: This involves complex investigations to diagnose and monitor disorders of amino acid and fatty acid metabolism, organic acidurias, and glycogen storage disorders to name a few.

Molecular Diagnostics: This subspecialty is focussed on techniques rather than a specific area of medicine. It involves analysis of specific biological markers. It has a broad reach across infectious disease identification, oncology testing, coagulation, and human leucocyte antigen typing.

Point-of-Care Testing: These devices permit the provision of clinical diagnostic tests close to the patient. Whatever methodology, the requirement for good laboratory technique and quality assurance is critical. The management of point-of-care devices and the training and competence assurance of the staff using them should be under the governance of the laboratory. Most laboratories have a team dedicated to this area.

Therapeutic Drug Monitoring: Measurement of drugs, or their metabolites, to ensure that the correct therapeutic level is achieved to have the desired effect and to monitor for toxicity.

Toxicology: Investigation of samples for the presence of drugs of abuse

Virology: The identification of a virus, or antibodies indicating a viral infection, in samples. Examples of common virology tests include testing for the range of hepatitis viruses (a-e), HIV, herpes, Epstein-Barr and, of course, in recent times Sars-CoV-2.

Laboratory Information Systems (LIMS): As evidenced by the cyber-attack in 2021 laboratories are heavily dependent on information systems. Such systems can track a sample seamlessly from order to result ensuring confidence in the result patient match. Within the laboratory analysers are interfaced to the LIMS permitting significant efficiencies. The national disease surveillance system relies on the LIMS for reporting. Indeed, in the tracking and tracing of individuals with COVID, extracts from the LIMS played a crucial role. The staff supporting these systems are charged with verifying them and extracting data to answer clinical queries.

Quality Management Systems: It is imperative that the clinicians can trust the quality of the services provided by the laboratory. Accreditation to the ISO 15189 standard provides that assurance. There are teams in the laboratories ensuring that internal quality control and external quality assurance are acceptable. They ensure that the uncertainty of measurement is known. They manage systems for document control, incident management, risk assessment, change management, and quality improvement.

Overview

The aforementioned survey covered a total of 2871.2 WTE professionals of varying grade and roles. The diagram below depicts the proportionate split of individuals by specialty within their respective laboratories. This includes scientific staff as well as other laboratory roles such as Quality managers and laboratory aides, among others.

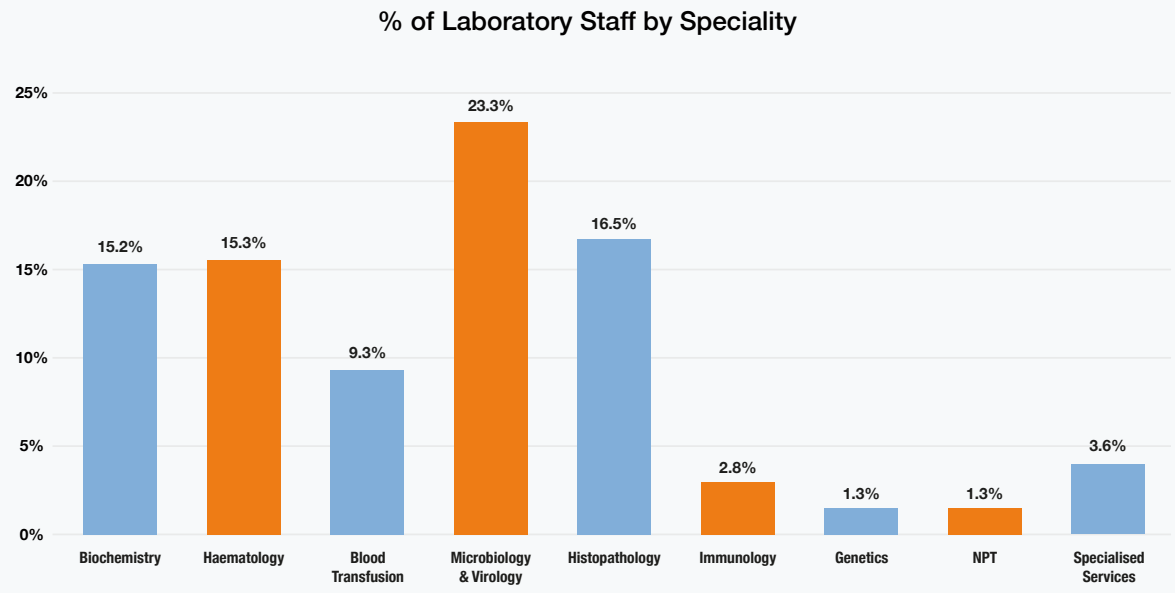


Figure 4: % of Laboratory staff per specialty (per survey)

Scientific Disciplines

The below sub-sections depict and describe the roles of the three primary scientific professions working in Ireland as provided by the professions themselves, including an overview of their demographics. They are all integral to the overall provision of service and are shown in alphabetical order, before subsequently discussing allied health professionals working within the laboratory. Outside the laboratory, it is noted that all scientific professions play an active role in many aspects of healthcare and education including but not limited to:

- The organisation and active participation in MDTs, case presentation, and grand rounds.
- Assessors in EQA schemes.
- Authors/contributors to international best practise guidelines.
- Authorship of peer reviewed scientific papers.
- Peer Reviewers of scientific papers.
- Expert advisory services (national and international).
- Invited speakers at national and international conferences.
- Teaching, training, and thesis supervision.

Clinical Biochemists

Overview

Clinical biochemists work alongside medical and scientific colleagues to provide diagnostic services in biochemistry, near-patient testing and specialised services including maternity and paediatric services, drug treatment centres, specialised endocrine services and national services such as the national metabolic laboratory and the National New-born Bloodspot Screening Laboratory. The contribution of the clinical biochemist may be defined through clinical, scientific, management and leadership roles in biochemistry and specialised laboratories. Consultant clinical biochemists lead and supervise the provision of clinical biochemistry services, provide expert advice on complex biochemical testing, and contribute to MDT's.

The role of the clinical biochemist is to provide expert interpretation of results, scientific and clinical advice (once suitably qualified and within scope of practice), participate in multi-disciplinary teams, input into grand rounds and case conferences. Furthermore, the consultant and principal clinical biochemist provides teaching, training, and thesis supervision for all grades of scientific staff, NCHDs and other HSCPs. Clinical biochemists lead service developments such as the introduction and expansion of specialised endocrine services at the Mater, St James's, St Vincent's and Galway University hospitals, the expansion of the National New-born Bloodspot Screening Programme, and the establishment of a gestational trophoblastic disease service in Cork University Hospital. They play an active role in translational research and consultant clinical biochemists hold honorary academic positions. Clinical biochemists contribute to national and international scientific and clinical programs through their representation on national and international committees.

Demographics

The survey conducted as part of the strategy covered 56.4 WTE Biochemists of varying grades. *Figure 5* depicts the composition of scientists by level of seniority.

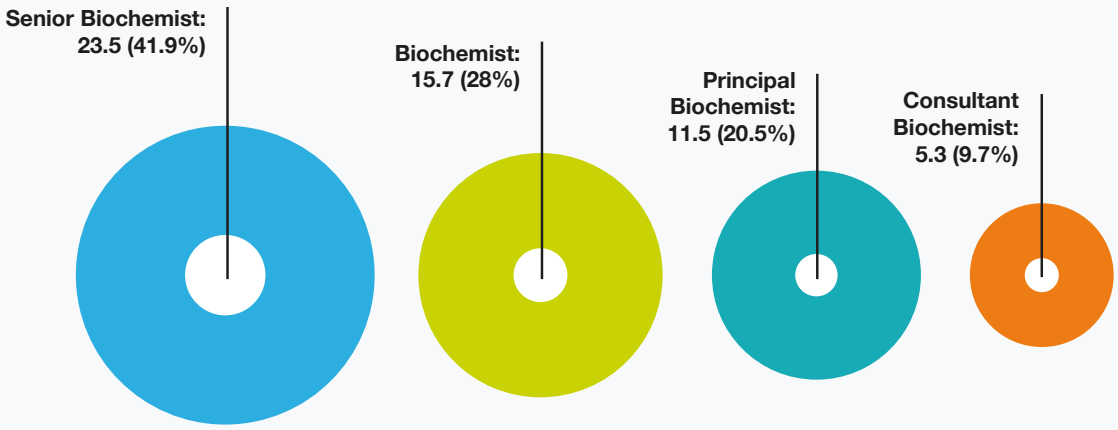


Figure 5: Biochemists by grade included in the survey

The above data represents only those in employment at the time of the survey and does not incorporate funded WTEs that currently remain vacant. The results of our survey found there to be the following vacancies amongst Biochemists:

- **Consultant Biochemist:** 18%
- **Principal Biochemist:** 26%
- **Senior Biochemist:** 2%
- **Biochemist:** 25%

In the HSE Staff Census (HSE, March 2022), 72 WTE in non-consultant clinical biochemists were noted. Of those, the distribution by seniority was as follows:

- **Consultant Biochemist:** 7.2 WTE
- **Principal Biochemist:** 14 (20.1%)
- **Senior Biochemist:** 38 (50%)
- **Biochemist:** 20 (29%)

Clinical Scientists

Overview

Clinical scientists are scientists that work alongside medical and laboratory colleagues to provide diagnostic and advisory services within a healthcare setting. Their contribution in healthcare includes clinical, scientific, research and innovation, management, and leadership roles in specialised laboratories. Clinical scientists are most abundant in in the genetics and genomics field.

As the role of genetics and genomics has expanded across medical specialities in healthcare, so has the requirement for clinical scientists. Their role in diagnostic testing spans all life stages of the patient journey from prenatal to adulthood and even post-mortem. Clinical scientists contribute to screening, predicative testing, carrier testing, disease diagnosis, and disease monitoring which allows clinical decision making

around patient management, reproductive decision making, and treatment stratification. In addition to authorising diagnostic test results, clinical scientists also decide reflex testing, provide result interpretation, and provide follow-up advice such as additional testing on the patient or segregation studies.

Within Ireland, clinical scientists work in referral services and specialised laboratories. They work across several key disciplines, including:

- **Rare/Inherited disease** – It is estimated that approximately 80% of rare disease has a genetic origin. Clinical scientists provide diagnostic information by analysis of a single genes, gene panels, exomes, or whole genome analysis. The result can end the diagnostic odyssey and provide valuable information for disease management and additional family studies.
- **Cancer** – Clinical scientists deliver a molecular profiling service to support cancer diagnosis and treatment. This includes cancer molecular diagnostics, cytogenetics, medical genetics, and cancer research. They are responsible for identifying significant chromosome and other genetic changes by means of karyotype analysis, FISH and molecular techniques and providing scientific interpretation of the results.
- **Pharmacogenomics** – Clinical scientists assess gene variants affecting an individual's drug response in a similar manner they assess gene variants associated with diseases. Clinical decisions can be made based on the genetic data by adjusting the dosage or choosing a different drug.
- **Infection Disease** – Clinical scientists participate in the development and implementation of infectious disease detection. Sub-disciplines include molecular virology, molecular microbiology, viral serology, and surveillance.

Demographics

The survey conducted as part of the strategy covered 27.7 WTE clinical scientists of varying grades. *Figure 6* shows the composition of scientists by seniority.

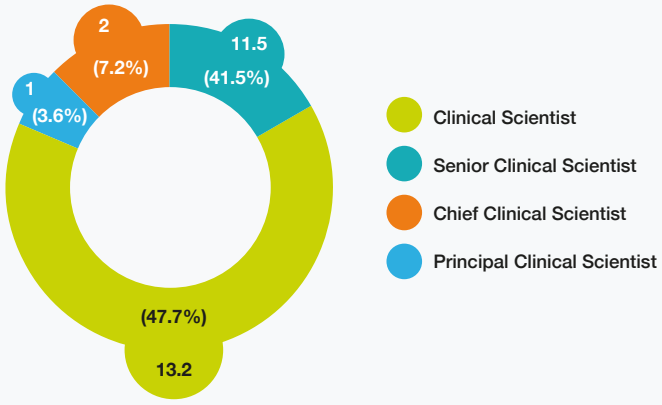


Figure 6: Clinical scientists by grade included in the survey

Whilst clinical scientists can work in a variety of specialties, the majority work within genetics and this is the case for all clinical scientists at senior/principal/chief levels. Of those at the basic grade, two WTE work in microbiology and virology, 7.5 work in genetics, and the remaining 0.7 WTE within histopathology. Currently, in the absence of a specific grade code for clinical scientists, they are typically employed on the medical physics pay scales and mirror that grading structure. This means it is not possible to provide comparison figures from the HSE staff census data. Furthermore, there is an awareness that many more clinical scientists work within the Irish health system and were unfortunately not captured in the returned surveys.

Medical Scientists

Overview

Medical scientists represent the largest body of scientific staff working in the Irish health service and work in all disciplines and sub-disciplines of the laboratory. Medical scientist is a legally protected title, regulated by CORU, and state registration is mandatory to practice in Ireland. It is a continually evolving and dynamic profession offering a variety of career opportunities including specialised laboratory work, research and development, and laboratory management. Continuous professional development (CPD) is a necessary requirement for state registration.

Medical scientists are an integral part of healthcare delivery. They are involved in every step of the patient journey including screening for illness, infection prevention and control, risk stratification, acute presentation and management, diagnosis, monitoring disease progression, and evaluating treatment efficacy, discharge protocols and palliative care. They work alongside colleagues to provide services catering to the clinical needs of a wide variety of specialties and services. Medical scientists, as part of a multidisciplinary team, develop and deliver accredited, effective, and fit for purpose testing to acute hospitals, primary care, and specialist/sub-specialist services nationally. They contribute to national and international scientific and clinical programs through their representation and leadership on national and international committees.

Furthermore, medical scientists play a key role in the interpretation of results at MDTs, provide undergraduate and postgraduate teaching (including thesis supervision) for scientists and other HSCPs, and lead many national referral services including national reference laboratories. They provide expertise to numerous bodies including, but not limited to, National Clinical Pathology Programme WGs, HPSC Scientific Committee, National Cancer Control Programme (NCCP), and the Health Information and Quality Authority (HIQA).

Demographics

The survey conducted as part of the strategy covered 1732.8 WTE medical scientists of varying grades. *Figure 7* depicts the composition of scientists by level of seniority, with 'other' indicating responses where no grade code was input.

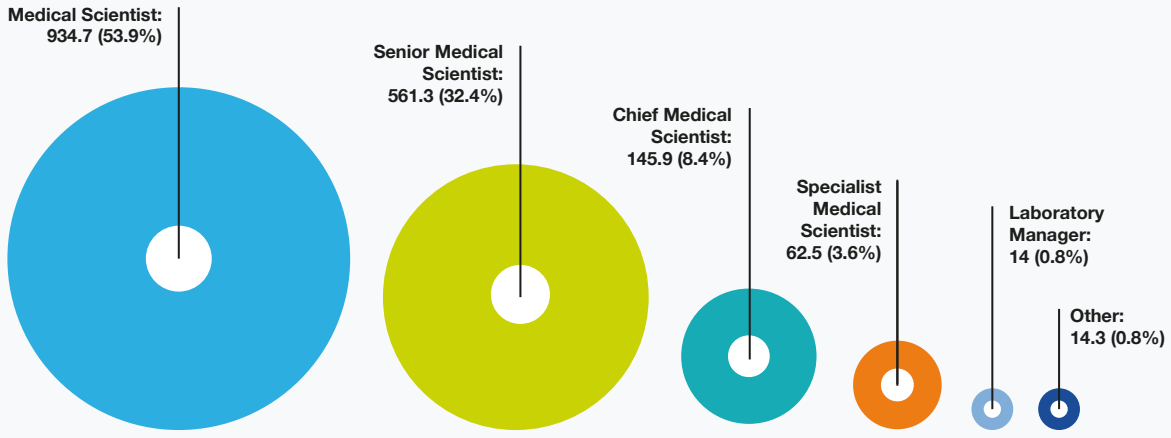


Figure 7: Medical scientists by grade included in the survey

The above data represents only those in employment at the time of the survey and does not incorporate funded WTEs that currently remain vacant. *Figure 8* demonstrates the percentage of total posts that remained vacant at the time of survey completion and is again analysed by level of seniority. The figures recorded during the survey are keeping with those of the HSE Census which documented 2,060 WTE medical scientists in the HSE, in addition to 77 undergraduate medical scientists. Of note, said census incorporated scientists working outside of acute hospital laboratories.

Of the 1,983 WTE qualified medical scientists documented in the census; similar proportions of seniority were seen:

- **Medical Scientist:** 1,041 (52.5%)
- **Senior Medical Scientist:** 697 (35.1%)
- **Specialist Medical Scientist:** 83 (4.2%)
- **Chief Medical Scientist:** 219 (11%)
- **Laboratory Manager:** 26 (1.3%)

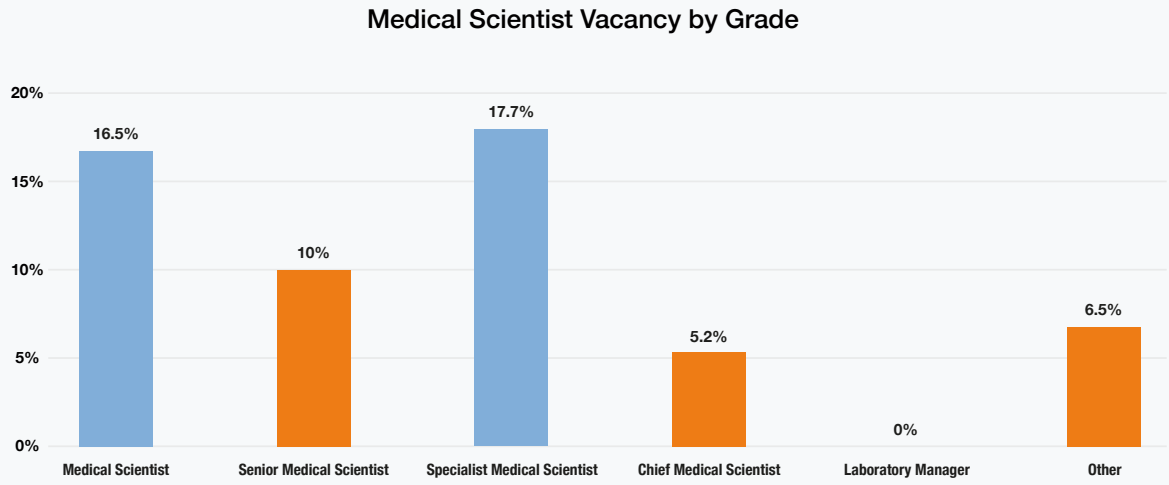


Figure 8: % Vacancies of medical scientist per grade within the survey

Medical scientists work across various specialties within laboratory medicine with the largest portion working in microbiology and virology. Division by specialty is demonstrated in *Figure 9*.

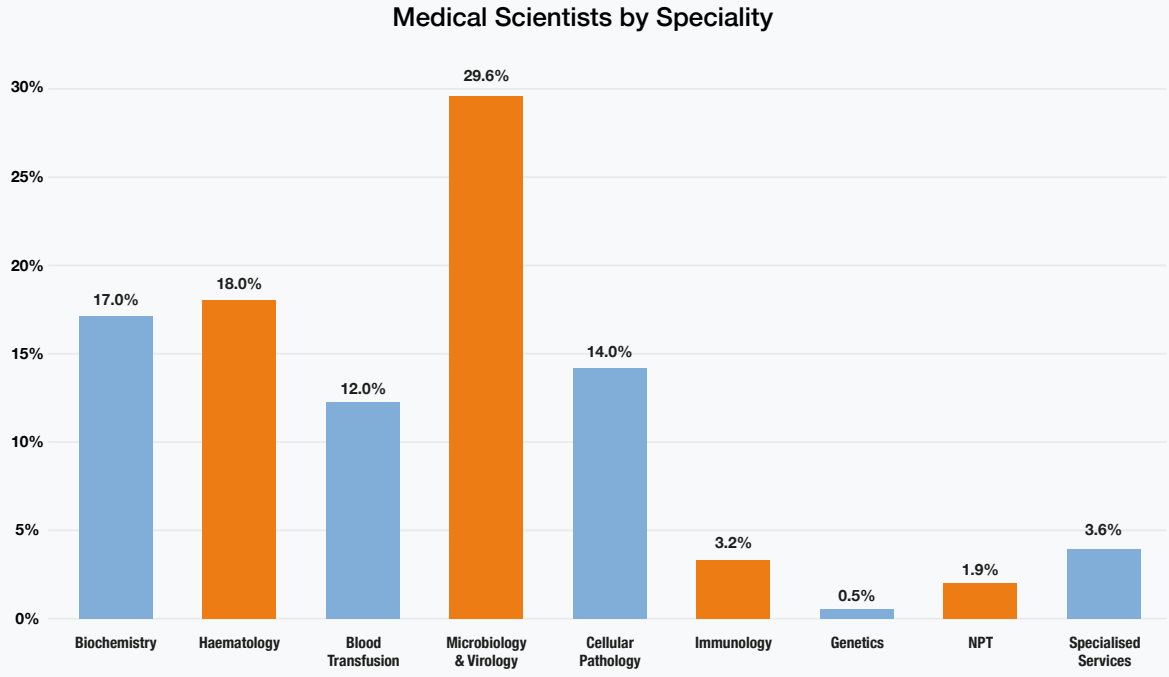


Figure 9: Medical scientists by scientific specialty

Medical Laboratory Aides

The role of the medical laboratory aide (MLA) is key to the efficient functioning of medical laboratories across the country. MLAs play a vital role in assisting the laboratory scientific staff in the execution of their duties. The responsibilities of a laboratory aide are highly adaptable and flexible, as they are contingent upon the specific requirements of each individual laboratory. These responsibilities encompass a wide range of tasks, including sample preparation, equipment maintenance, data entry, and ensuring the overall smooth operation of the laboratory environment. Notably, a survey of lab aides in Ireland has revealed that the educational qualifications of these professionals are diverse, with over 50% holding a level 8 scientific qualification and almost 9% possessing a level 10 qualification. This diversity in educational backgrounds underscores the importance of their role in providing valuable support to the broader healthcare system.

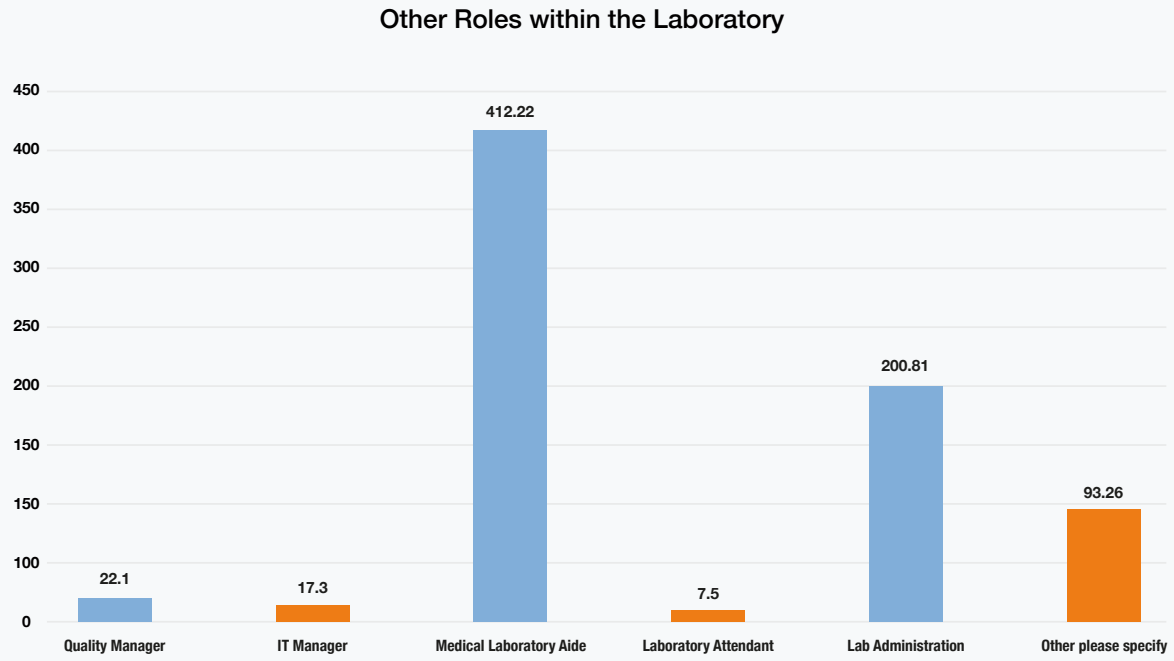


Figure 10: Number of other laboratory staff included in the survey

Pathologists

The role of pathologists and associated manpower requirements have been extensively evaluated and reported by National Doctors Training and Planning (NDTP). Resultantly, such efforts have not been duplicated within this report. Pathologists play a key role in governance and clinical leadership of laboratories, and are involved in determining appropriate tests, undertaking and reporting tests, and advising about their interpretation and subsequent patient management.

The Faculty of Pathology at the Royal College of Physicians of Ireland is the national professional and training body for pathology in Ireland. The faculty is accredited by the Medical Council of Ireland and meets the strict standards required to deliver postgraduate specialist medical training in six pathology specialties. Training of pathologists follows medical training at both undergraduate and postgraduate levels, and is structured, validated, and assessed. Qualification requires development of a portfolio of competencies, one of which is successful completion of the FRCPath examination. Qualification for many aspects of the pathologist's role is outside of, and in addition to, the FRCPath examination.

The six pathology specialties recognised by the Medical Council are chemical pathology, haematology, histopathology, immunology, neuropathology and microbiology. Each specialty has recognised special interest areas, and eligibility for such special interest posts requires additional certified training following completion of higher specialist training.

Services provided by pathologists vary considerably between specialties. Clinical liaison which involves advising on test choice, interpretation of results and patient management is a key medical role across all disciplines. Pathologists are involved in specimen preparation, analysis, and reporting, as well as laboratory consultations discussing complex sets of results, and MDT participation. In line with the international experience (Cheung, 2015), both the volume of laboratory testing and the complexity of interpretation has been increasing in all disciplines. Service improvements which impact pathologists may be result from pathologist-initiated quality improvements or from initiatives implemented in other parts of the health services.

Histopathologists and neuropathologists provide autopsy services. Many post-mortem examinations (PMEs) are ordered by the coroner and conducted as independent work outside of HSE contracts (RCPI, 2019). Consented PMEs provide important feedback on care provided prior to death, help understand disease processes, and complications, may be an important component of bereavement care, and particularly in paediatric and perinatal deaths, may inform future reproductive choices.

Pathologists provide direct patient care in haematology, immunology, microbiology, and chemical pathology, including inpatient consultations, outpatient clinics, ambulatory care, and in-patient care in some disciplines.

In addition to laboratory duties, microbiologists are typically responsible for antimicrobial stewardship, infection prevention and control, and advise on management of patients infected with complex/resistant microorganisms. Microbiologists provide direction for public health laboratories, including public health and food and water laboratories, in hospitals and the community.

Pathologists work closely with all scientific professions, and support staff, and collaborate with the directorate management team to provide, lead and develop the laboratory medicine service in their discipline. Pathologists will also fulfil clinical director/laboratory director roles, which are central to the laboratory medicine directorate management team. The Clinical Director role involves collaboration and liaison with clinical directors throughout the hospital to optimise the contribution of the laboratory medicine directorate to patient care and contribute to continuous quality improvement of patient management.

A key difference between medical professionals and other scientific professions relates to the guidance on managing individual patient care. Advice relating to patient treatment and care is provided by medical professionals.

A detailed description of pathologists' roles is outside the scope of this report.

Nationwide Survey Responses

Staffing Structures

Laboratories responding to the survey were asked if they found the current staffing structures to be appropriate to workflow in their laboratories. 29 of the 31 respondents answered, with just over half (55.2%) indicating that they were. Of the 55.2% who felt they were appropriate, almost half (24.1% of total) qualified the answer with text indicating that it was dependent on filling posts or maintaining workload at current levels.

Of those that answered no, the following response indicates the reasonings:

"Year on year increase in samples sent to the laboratory. Increased complexity of tests requests which has resulted in an increase in referred tests and the tracking of same. The combination of increased testing with unfilled posts has resulted in slower TAT and a decrease in the quality of the work carried out."

Of those that answered with a qualified yes, the following responses give a flavour of the comments added:

"The current staffing structures are appropriate to workflow, but only if staffing is maintained at optimal levels, which is not the current situation."

When asked if there are specific alternative structures that might be more appropriate in terms of enhancing workflow, 25 of 31 respondents proffered an opinion. Many highlighted deficiencies specific to their sites, however, it was possible to identify common themes in the responses. The need to provide for staff development was a key theme, with 16 of the 25 (64%) identifying a need for senior roles for scientific staff and/or a need to facilitate entry level access to scientific pathways, particularly for the laboratory aide workforce. Although not specifically requested, seven respondents suggested IT and/or automation upgrading as a means to lessen the impact of staffing deficits. Examples include:

"An electronic ordering solution would create immediate wins for the laboratory as lab aides are preoccupied with manual booking throughout the day. Advancement in instrumentation with additional robotics would also enhance workflow, however, additional space would be required to accommodate this solution."

In summary, existing staffing structures are considered appropriate for most sites by the laboratory manager but, as many respondents delineated, only with a full complement of staff. Prominent suggestions to improve deficits included staff development, creation of additional senior positions, facilitating entry to scientific professions, and upgrading of IT/automation infrastructures.

Achievement of National or International Targets for Laboratory Turnaround Times

Respondents to the survey were asked whether there are national or international targets for laboratory that are not being achieved within their laboratories. All 31 respondents answered with 61.3% indicating that there are turnaround target times which are not being met.

Respondents who indicated that targets for turnaround times were not being met were asked to identify the key preventative factors to ensure patient needs are met. *Figure 11* indicates the most frequently mentioned reasons.

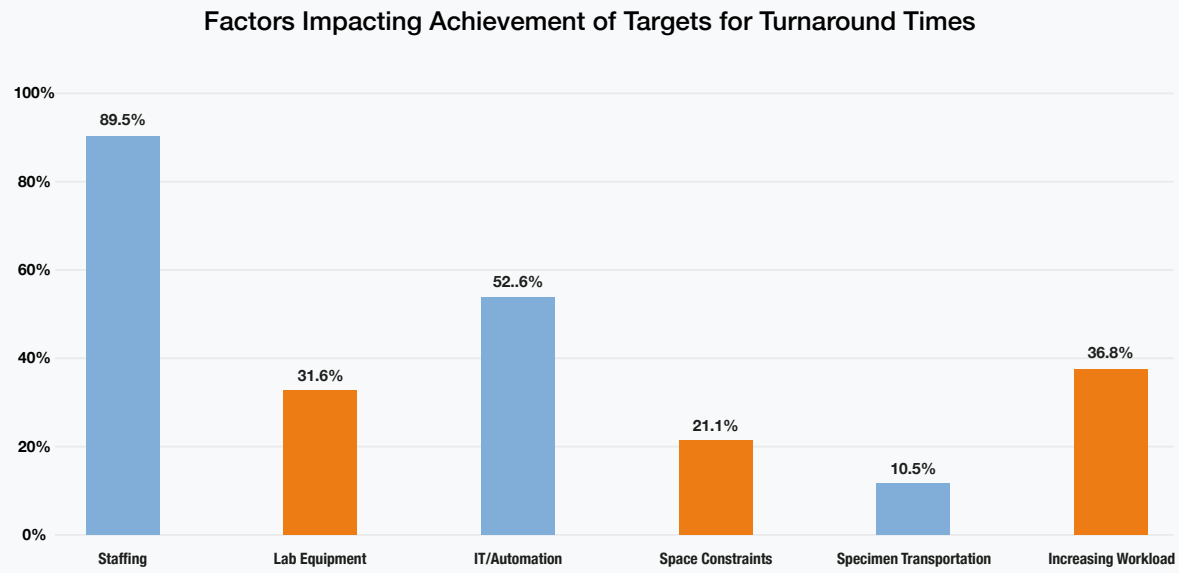


Figure 11: Factors impacting achievement of target laboratory turnaround times

While staffing was identified as the single factor by some respondents, many elicited multiple factors contributing to the challenges in meeting target times.

"This is multifactorial – although the staff are competent and well trained, barriers to improving TAT include poor IT, skeletal requesting, LIMS system, manual nature of sample processing, skeleton staff out of hours. Some of this will be addressed with planned improvements however some of these concerns are outside the control of the laboratory."

"The low staffing numbers in all departments require the work to be prioritised, this results in some testing not meeting the required TAT. Laboratory equipment and the lack of effective IT solutions also prevent TATs being met."

Staffing issues include low staffing numbers and vacancies with many specifically referencing difficulty recruiting medical scientists, shortages of consultants, retirement, shortages of administrative staff, and burnout. The potential impact of restoration of working hours to pre–Haddington Road Agreement levels was also noted.

Increases in workload without corresponding increases in human resources was cited among many responses. Specific reference was given to increased referrals from primary care in addition to increased sample numbers as a direct result of new services being introduced in primary/secondary care. Several responses identified specific specialties experiencing increased workloads including blood sciences and microbiology.

In addition to laboratory equipment, insufficiencies in information technology infrastructures were reported frequently with specific references to MedLIS and existing systems that are beyond their expiry date. Hand labelled and handwritten requests with laborious order entry processes are described. One respondent highlighted the requirement of staff resources for validation and implementation in the context of new automation and identifies the potential for this development to impact TATs in the absence of sufficient staff resources. Space is noted as a constraint in increasing automation. One respondent noted that they have to refer tests off site as equipment, space and staffing are insufficient.

Specimen transportation was also noted as a factor, including distance from referral laboratory, with the requirement for more near-patient testing highlighted.

Unmet Needs

Respondents were asked: "Are there unmet needs within your laboratory that could be developed through enhancing existing roles within your service? Please expand." Of the 31 respondents, 27 chose to comment.

Laboratory services beyond the traditional role of result generation were predominant in the replies, areas such as training of staff, near-patient testing (NPT) Services, advanced practice initiatives, demand management and quality processes.

The following examples are representative:

"Due to the current vacancy level in all labs if there is a solution to increase number of medical scientists then there will be a significant training requirement for each lab to train staff to an appropriate level."

"Our service requires scientists who specialise in clinical and management services to be equally valued, we need more scientists with FRCPath to sustain and meet the clinical demands of a modern pathology service and we need more scientists with business and management capabilities with MSc and MBA in order to meet the operational demands we face. Both pathways should be valued equally."

"NPT is a huge need within the hospital and an area that is quickly developing, but we only have got sanctioned currently for 0.5 WTE which is totally insufficient to meet service needs."

The responses indicate that respondents perceive a lack of local service development to match increased demand. Day-to-day tasks are drawing staff away from improvement initiatives which are required to meet the needs of a continuously evolving service and healthcare system.

Equipment Requirements

29 of the 30 responses stated that additional equipment is required. Laboratories were asked to identify if this issue was a result of an equipment replacement or upgrade requirement and just over half of laboratories chose the new equipment option (55.2%). The comment section of this question allowed for elaboration. On analysis, a clear message was communicated – both upgrades and new equipment are required. Deficits in equipment affect all disciplines within the acute hospital laboratory landscape.

While laboratories were not explicitly asked to itemise equipment deficits many chose to do so and the items mentioned ranged from basic laboratory equipment such as fridges, freezers, and incubators to advanced technologies including flow cytometers and sequencing platforms. Multiple laboratories stated that there is insufficient capacity within the current platforms to meet the demands of the current and future service. Some personalised accounts of the challenges brought about by inadequate equipment are detailed below:

"Lack of adequate equipment requiring outsourcing"

"Unprecedented sample numbers from GPs due to the Sláintecare chronic disease programme has left blood sciences at maximum capacity and no space to install additional analysers."

Other Requirements

Inadequate IT infrastructure was highlighted by many respondents in this section of the survey. The need for a modern IT infrastructure, order comms and a robust LIMS was referenced by many, such as below:

"Laboratory service could benefit from major ICT resource. Systems in place are not up to date and add to the work rather than lean up the processes."

Near-patient testing and the laboratory resources required to support this were also mentioned:

"Near-patient testing needs personnel and quality improvement."

Other suggestions included the provision of a central HSE location from which GPs could obtain laboratory consumables, the funding of medical scientists for postgraduate/further education and a review of the current on call and working patterns.

Challenges

Overview

In the final section of the survey, participants were asked to identify the top three challenges to practice in their respective laboratories. The main issues identified were clear and reflected in their responses across the entire survey.

As seen in *Figure 12* below staffing shortages, IT/automation, and a lack of space are the greatest issues currently faced by laboratories in Ireland. Other challenges stated included:

- Allowing senior staff protected time off the bench to engage in development of the service
- Demand management
- Connectivity; including lack of interface for some analysers and lack of Wi-Fi
- Laboratory location

IT and automation were the most widely reported challenge faced with 90% of laboratories citing it as an issue. Despite technology rapidly advancing, most laboratories report a lack of development in IT and automation, resulting in many processes being carried out manually and resultantly straining resources.

Noted repeatedly was the lack of order comms or an electronic transfer system of results between labs. Of the laboratories included in the survey only 26% reported having order comms for in-patient services, 16% for out-patient services and 3% for primary care services. A common theme was evident that upgrades and investment is needed to improve IT and automation.

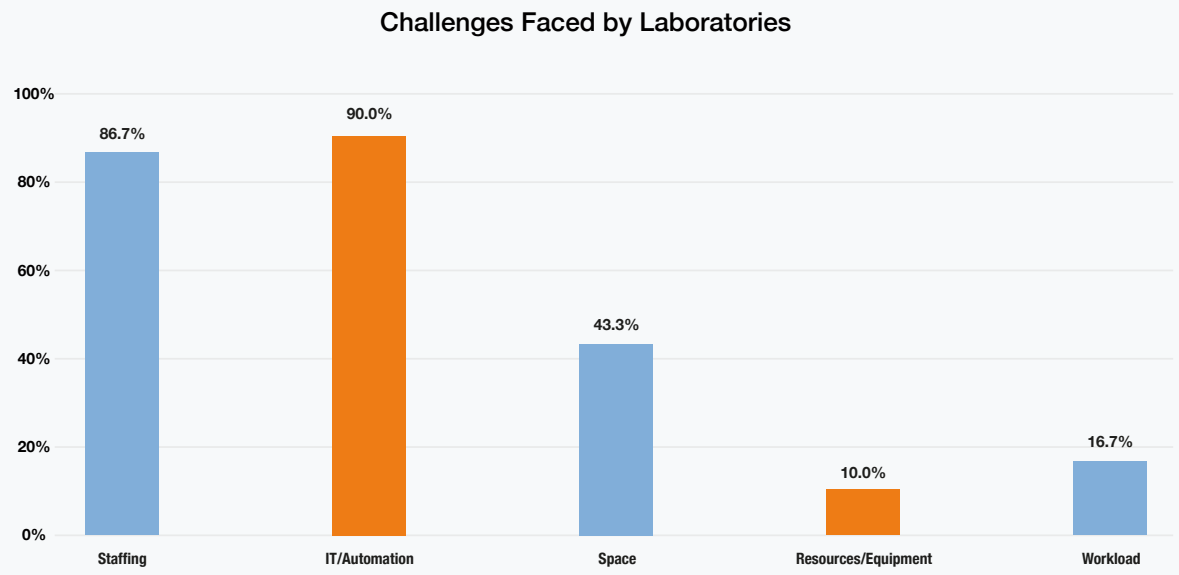


Figure 12: Challenges faced by laboratories

86.7% of laboratories included in the survey reported issues with recruitment and retention of staff. The lack of laboratory staff is impacting routine service as well as future service development and demand. As a result, Laboratories are increasingly reliant on outsourcing to maintain routine services. In some cases, the shortages have resulted in labs being unable to offer parental leave or other flexible working options. Recruitment and retention of staff is impacted by overly laborious sample handling processes and working in laboratories where there are too few staff to free up staff for quality system work, CPD, service development, process improvement and staff development. As depicted in the figure below, there are shortages of staff at all levels.

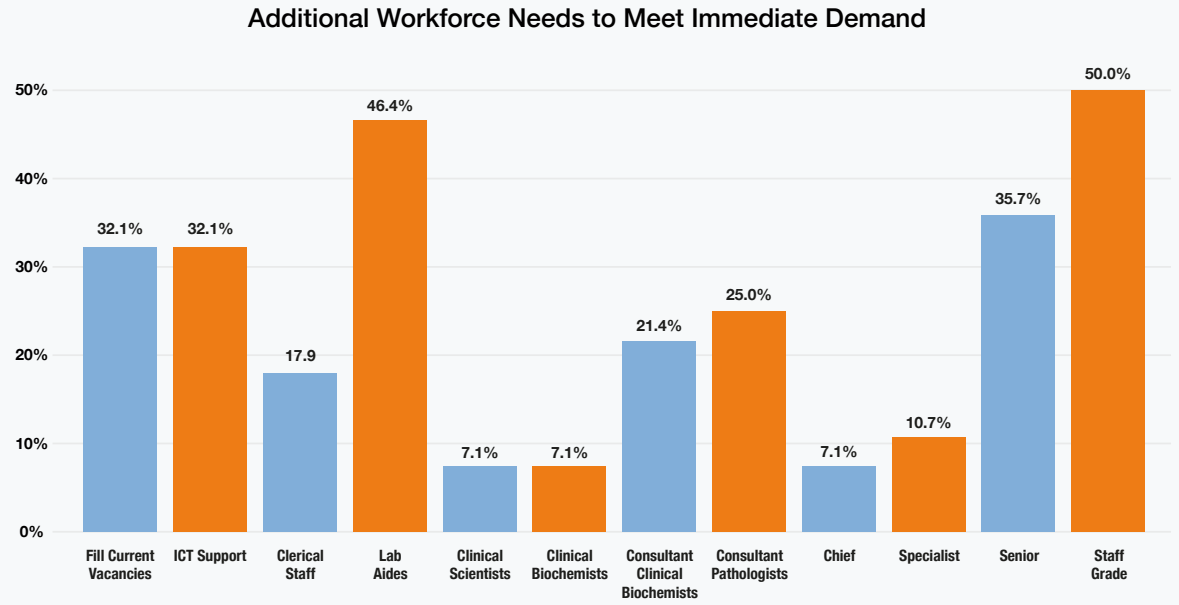


Figure 13: Percentage of laboratories reporting additional workforce needs at each level

Microbiology Reference Laboratories

Overview

Microbiology reference laboratories in Ireland provide specialist services (as described by the European Centre for Disease Prevention and Control) and predominantly exist as services within acute hospital laboratories. All microbiology reference services currently fall under the governance of the HSE, with the exception of the National Virus Reference Laboratory (NVRL). The NVRL sits as an unincorporated entity within University College Dublin (UCD), despite the majority of their work/funding being provided by the HSE. From a governance perspective the President of UCD retains oversight of the NVRL through an appointed advisory committee, chaired by the College Principal of Health and Agricultural Sciences.

Public Health Microbiology is defined by ECDC in their technical report that was published in 2013 – *"Core functions of Microbiological Reference Laboratories for Communicable Diseases"*. It explains that:

"'Public health microbiology' is a cross-cutting area that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease. It requires laboratory scientists with the ability to work effectively across disciplines, particularly epidemiology and clinical medicine." (Jasir, 2013)

Microbiology reference laboratories are critical for the development of high-quality clinical and public health microbiology services throughout Europe. They play a key role in the detection, monitoring, outbreak response, and provision of scientific evidence to prevent/control infectious disease outbreaks. Strong collaboration exists between member states' respective reference laboratories, thus contributing to both the mandate of the European Centre for Disease Prevention and Control [Regulation (EC) No 851/2004] and fulfilling obligations placed on Member States by the International Health Regulations (WHO, 2005). The above referenced technical report outlines the five core functions of reference laboratories, which are summarised below:

Function 1: Reference Diagnostics

The reference laboratory has state-of-the-art validated laboratory methods in operation and the ability to deliver accurate confirmation of diagnostic results within its field of expertise. This may include the analysis of samples in a variety of areas, such as the verification of results (e.g., detection or confirmation) reported by external laboratories, the detection of specific microbial markers, and the investigation of atypical samples.

Function 2: Reference Material Resources

If necessary, the reference laboratory develops and maintains – in accordance with international standards and procedures – a collection of relevant reference material that is to be shared with laboratories and organisations that request such materials. These materials can include reference laboratory strains and cultures, clinical isolates, sera, genetic materials, etc. These resources are important for the varied purposes of quality assurance systems, method evaluation, and validation.

Function 3: Scientific Advice

The reference laboratory is a resource and coordination point for expertise within its specific area and shares information and advice with relevant stakeholders, often as single points of contact for national or highly specialised services. This can include technical advice on methods and procedures, scientific support, and advice on the interpretation and relevance of laboratory findings on pathogens to relevant public health authorities (policy makers and public health professionals).

Function 4: Collaboration and Research

The reference laboratory is at the forefront of technological and scientific development in its field of expertise, particularly in areas relevant to public health action. Contacts with regional and international laboratory networks as well as related initiatives should be established and maintained. Examples of collaboration are involvement in EU and other international disease-specific networks, network activities of regional laboratories, or global initiatives via the World Health Organisation (WHO) or the US Centre for Disease Prevention and Control.

Function 5: Monitoring, Alert, and Response

The reference laboratory performs or contributes to surveillance activities or has established channels of communication with the national surveillance body to regularly report incidence data and provide an 'alert function' for unusual occurrences. These can include failure of a diagnostic test, detection of changes in incidence, virulence, drug resistance, emergence of a possibly infectious disease of unknown aetiology, etc. In the case of an outbreak, the reference laboratory supports outbreak investigations, e.g., by offering diagnostic services, advice, and technical expertise, and, upon request, provides surge capacity for diagnostics.

In 2021, the HSE commissioned an internal report analysing existing Public Health Microbiology and Virology Reference Laboratories. As part of the process, they gathered information on existing services which are outlined in Appendix 12. The draft report (HSE, 2022) published internally made the following key findings:

1. Ireland's Public Health Microbiology and Virus Laboratories (PHMVL) services play a central role in health protection within Ireland and contribute to health protection within the EU. The SARS-CoV-2 pandemic has highlighted the importance of this capacity as never before. PHMVL services are also key to sustaining economic activity in particular the agri-food sector and the tourist sector by providing assurance of food safety and bathing water standards.

2. Ireland has good PHMVL capacity by comparison with many EU member states. It has an excellent cadre of medical and scientific expertise, strong technical capacity, and high-quality standards. This is evident from the accreditation status of the laboratories and from the contribution of Ireland to many ECDC surveillance activities and review groups and contributions to other international fora. There are also strong relationships with local and regional clinical services, Public Health and Environmental Health services, the Food Safety Authority of Ireland and with local authorities.

3. The volume of activity undertaken by PHMVL services is evident in that approximately 361,544 samples were processed by the Microbiology Reference Laboratories in 2019 and approximately 1,050,299 tests were reported. Approximately 52,756 samples were processed by the Food and Water Microbiology Reference Services and approximately 115,596 tests were reported. It should be noted that 2019 data is provided as 2020 data was reduced due to COVID-19 response.

Whilst there were a number a number of recommendations made throughout the report, the following key recommendation was made:

"That central strategic leadership and management of these services is essential to address current and future needs. This report proposes a plan, pathway, and timeline for progression towards an integrated and comprehensive Public Health Microbiology and Virology Laboratory services (PHMVLS) that preserves existing strengths, optimises use of existing resources, and identifies additional resource requirements."

It is proposed that separate funding be available for Reference Laboratory functions that would be controlled by a Central PHMVLS Board, retaining oversight of the national service. The working group acknowledge this report and the time in which it was published. With the roll out of HSE Health Regions, laboratory funding needs to be considered.

The National Virus Reference Laboratory (NVRL)

The NVRL currently falls outside of the governance of the HSE and instead operates under a memorandum of understanding, renewed on a 5-yearly basis. It is advised by both the PHMVL Review and this Report that the position of the NVRL moving forward is evaluated considering the laboratory is predominantly funded by the HSE with 95% of its work coming from the Irish Public Health Service. It is essential that the NVRL exists as part of any integrated national reference laboratory network and as part of an academic healthcare system.

UCD NVRL is the principle diagnostic virology laboratory in Ireland with samples being sent from hospital laboratories within the HSE Health Regions and from general practitioners. It also acts as a confirmatory and reference centre for those laboratories that perform their own initial viral investigations as well as participating in disease surveillance programmes on behalf of the Department of Health (DoH). While all hospitals use the NVRL, those hospitals outside of Dublin generally perform most of their routine virology-related work on-site and only send specialised work to NVRL.

Originally established in 1963 on a not-for-profit basis, the NVRL was set up at the behest of the DoH, in order to provide national poliovirus surveillance and to fulfil Ireland's World Health Organisation mandate, on behalf of the DoH, as the WHO accredited National Influenza Centre (NIC). Subsequently, the NVRL with the approval of the DoH has expanded to provide a diagnostic and reference function for the Irish health service.

The NVRL played a vital role in Ireland's response to the SARS-CoV-2 pandemic – they provided hands-on laboratory capacity, clinical oversight to a number of laboratory partners as well as advisory support/direction with respect to the national pandemic response. They also upscaled their own capacity through the establishment of the Backweston satellite site – a move supported by the HSE who procured required equipment and provided financial resources to extend the headcount. Moving forward, the NVRL have been asked to form the first line of defence should any pathogen require mass testing whilst also acting in an advisory capacity to the State as required. They will also lead out on viral surveillance through the provision of advanced whole genome sequencing capabilities.

In order to fulfil their proposed remit going forwards, it is recognised and accepted that a review of their current situation is required to guide required investments. This assessment is currently underway and incorporates reviewing their governance arrangements, staffing structure in addition to the underlying infrastructure to ensure the facility is fit for purpose. It has previously been recommended that the NVRL is fully integrated with other laboratories as part of an academic health system. This will help safeguard the needs of the population and Irish health service.

Section 2.0

Consider education and credentialing pathways to support professional development of laboratory staff with a broad-based educational approach that is reflective of their area of competence and expertise and aligned to evolving best practice standards and service requirements.

Introduction

This section serves to consider education and credentialing pathways to support professional development of laboratory staff. It considers the three scientific disciplines, summarising the challenges associated with current practice and provides recommendations on future enhancements.

Background and Context

Evidence shows that 95% of clinical pathways require input from clinical diagnostic laboratories services (National Institute for Health and Care Excellence, 2021), and that 70% of actionable data in relation to diagnosis comes from laboratory diagnostic investigations (ASCP, 2022). Clinical diagnostic testing takes place both within the laboratory and close to the patient in clinical settings (near-patient testing). The continuing technological and IT enhancements in diagnostic testing means that now and in the future training, education and professional development of laboratory staff is and will be the key to the effective development of clinical laboratory services. Laboratory scientific staff encompasses clinical biochemists, clinical scientists and medical scientists. Postgraduate specialist training of medically qualified pathologists is not addressed in this report as Medical Council accredited training programmes are already in place, delivered by the Faculty of Pathology.

The creation of a continually developing and skilled laboratory workforce is key to the overall functioning, efficiency, and effectiveness of a range of clinical services across the health system. Opportunities for enhanced service provision and efficiency gains in the rapid diagnosis, appropriate management, and subsequent discharge of patients from costly acute settings by embracing new diagnostic services and technologies can be enhanced. Without an appropriate and effective clinical laboratory service, not only will there be delays in patient diagnosis and management but there are likely to be ever increasing costs associated with delayed discharges or misdiagnosis, impacting both the patient and their subsequent trust in the service. Litigation surveys in the US show that inappropriate testing, or misinterpretation of laboratory results is involved in 1 of 8 legal cases, hence effective laboratory services are also a patient safety issue.

Provision of near-patient testing (NPT) services to current ISO accreditation standards require clinical governance from the laboratory, to ensure assay verification and ongoing quality management, as well as training, troubleshooting, and strategic planning and development. There is considerable time required from laboratory scientists to establish or expand a NPT service. Therefore, expansion of NPT may exacerbate rather than assist with laboratory staff shortages, at least in the short term. Nonetheless, resourcing of NPT services with appropriately trained scientific staff must be optimised to ensure the quality of the NPT service meets the clinical need.

It is important to emphasise that resources directed to the development of the laboratory services workforce are investments that can generate significant returns. Coupled with the further automation of testing, a highly skilled workforce can provide information to improve clinical decision making, develop and implement new test methodologies which can decrease test turnaround times and identify significant efficiency gains both within laboratory testing pathways and general hospital/community referral pathways.

Given the current and future international recruitment difficulties being experienced by all health systems, investment in the training and development of laboratory staff might create a more promising career pathway that attracts and retains staff. It is, therefore, important that strategically the health service recognise the importance of the training, development, and career progression of all laboratory staff in the health services workplace.

Principles and General Approach

The health service should base its approach to the training, development, and career progression for all laboratory staff on current best practice. Laboratory staff represent a valuable asset and resource for the health service. With the rapid advancement of technologies in this area, training and development of laboratory staff must keep pace with these advances to support an efficient and effective health service in the future. Fundamental to the approach should be a respectful and equitable approach to training and development of laboratory staff.

The multi-disciplinary nature of laboratory medicine is critical to delivering an efficient service that is appropriate to the clinical needs of the health service. The configuration of services will vary according to clinical need. In small hospitals, multidisciplinary staff may facilitate an efficient service, while in larger busy level 4 hospitals, and particularly in the provision of specialist services, depth rather than breadth of knowledge and skills may offer benefit. The health service urgently needs to consider and integrate the developing credentialing and registration systems that will be relevant to the regulation of laboratory scientific staff. In addition, qualifications, training and, credentialling for laboratory support staff must be considered.

Maximising the Potential of Scientific Laboratory Staff

Overview

It is important for the health service to develop an integrated and unified system for the training, education, and career advancement of all laboratory staff. The approach should seek to maximise the scope of practice within each individual discipline relevant to their qualifications, training and experience whilst developing career opportunities that allow for enhanced inter-professional training (where appropriate) and service collaboration. It is important to note that this approach should appropriately value individual qualifications and career pathways. Optimising the potential of the scientific staff will maximise the contribution of laboratory services to a range of clinical programmes and as a result, impact overall population health. Moreover, the provision of career pathways that meet service needs, facilitate the implementation of technological advancements, and addressing scientific aspirations may result in enhanced staff retention and overall return on investment.

The health service should identify future service needs (including services currently referred outside of Ireland and services related to new technologies) and anticipate the changing healthcare landscape to ensure the profile of competencies and skills is evidence based. This profile should inform the development of its approach to training (including for the introduction of new technologies) as well as the development and career progression pathways for medical scientists, clinical biochemists, clinical scientists, and clinical services generally.

For the future development of laboratory services, the health service will need to develop and implement an approach that seeks to strategically align the range of scientific laboratory staff (and their differing skills and qualifications) relevant to the clinical service needs and the implementation of evolving technologies. In this context, this approach needs to be underpinned by clear recruitment, (undergraduate/postgraduate) training, and on-going professional development systems. It is recognised that these measures will take some time, and maintaining services requires a series of urgent actions to develop support staff, as well as leveraging automation and IT (see below).

In a broad outline, any training or career progression system should have the following strategic objectives:

1. Expanding and strengthening the scientific knowledge and expertise of the scientists.
2. Aligning skills development with service requirements as well as advancements in practice and technologies.
3. Development of inter-professional and collaborative training systems (where appropriate) to maximise development opportunities both within and across scientific professions and other professions where appropriate.
4. Training for all scientific professionals must be recognised and supported by the health service.
5. Supporting all laboratory scientific disciplines in the registration and on-going educational requirements of the registration system.
6. Develop and recognise current advanced practice, while developing strategy for specialist registration for those moving to more senior roles.
7. Development of return-to-work systems to support experienced scientific staff gain or renew registration status and/or experience following a period of absence from the workplace.
8. Ensure that there are clear role definitions and maps associated with each discipline, in accordance with local governance arrangements.
9. Development of support and assessment systems to allow for the transfer of staff between scientific disciplines and specialties (within qualification and registration boundaries) where skills or service need are required in individual laboratories.
10. A national mechanism for the development and approval of new higher specialist training posts.
11. Specific pathways for training and development of scientists in specialist services, which may comprise a single national laboratory. This may require collaboration with other jurisdictions and laboratories with specific expertise, as well as support of secondments.

Specialised Laboratory Services

There are a significant number of specialised laboratory services in Ireland across the laboratory medicine disciplines. These provide critically important national services or services that are specific to a clinical care pathway. They often are relatively small services, involve non-routine equipment, manual laboratory methods and require significant expertise to interpret the results. As such, training in these specialised areas may take a considerable period of time, in many cases 1-2 years to achieve technical competence and perhaps more to achieve competence to report results. There are no formal training programmes for these specialist areas. Scientific staff appointed to these laboratories are trained 'on the job' which is time consuming for a small service. These laboratories may be perceived as providing a narrow career experience or may not have adequate promotional opportunities. Therefore, the significant time invested in training is lost when a person leaves the laboratory.

Specialised services need support to train, retain and develop all relevant laboratory professions as new technologies emerge. Consideration should be given to collaborating with other specialised services in the UK/EU to develop training supports and/or a laboratory exchange programme taking into consideration what is appropriate to service needs. In addition, sub-speciality training (including placement and funding for secondment) should be considered for higher specialist training programmes to ensure there is a structured element of training for those who will be providing governance of these services.

Translational Research in Diagnostic Laboratories

Translational research in diagnostics allows advances made in basic research to be translated into routine use in diagnostic laboratories. Translational research is particularly important in services where CE-marked kits are not available for tests and methods must be developed in-house. Undertaking research and development such as this in a clinical laboratory has the benefit of developing the method on the site where it will be used and also allows the scientists undertaking this work to develop their skills and retaining these skills within the laboratory. The completion of a PhD would be highly desirable for scientists wishing to take up more senior roles in the laboratory.

There are programmes available that allow postgraduate research in an industry or employer workplace setting such as the Irish Research Council (IRC) Employment-Based Postgraduate Programme (IRC, 2022). The grant provides a contribution towards employment costs, academic fees, and direct research expenses. These grants can be used to fund masters or doctoral level research. The employer must commit to funding the remaining salary of the employee for the duration of the project and give the participant the time and facilities to complete the project.

There are many other different supports and funding opportunities available to scientists wanting to undertake postgraduate research at both masters and doctoral level. Organisations such as the IRC, Health Research Board (HRB), Science Foundation Ireland (SFI), European Research Council (ERC) as well as many charitable organisations provide funding for such projects and calls for applications happen throughout the year (see Appendix 2 for examples).

There can be challenges associated with undertaking doctoral level research while in full time employment:

- Ensuring protected time to complete work.
- Securing funding outside of an academic environment.
- Partnering with an academic supervisor.
- For larger projects, particularly PhDs, finding candidates who want to leave diagnostic role for a full-time research role.
- There may be limited opportunities for re-entry to highly specialised diagnostic areas if opportunities arise infrequently unless an employment-based grant is secured.

Career Progression

Clinical Biochemists

Routes of Entry:

Clinical Biochemists are employed in the Irish health service as clinical biochemists, senior clinical biochemists, principal clinical biochemists, and consultant clinical biochemists. At present, entry into the profession as a clinical biochemist grade requires one of the level 8 degree qualifications listed here. Eligibility criteria to progress are as follows:

- **Senior Clinical Biochemist:** MSc and three years' experience in clinical biochemistry/related discipline
- **Principal Clinical Biochemist:** FRCPath part 1 or PhD and five years' experience in clinical biochemistry/related discipline
- **Consultant Clinical Biochemist**: FRCPath or PhD and at least eight years' experience, of which five must be in clinical biochemistry

Principal grade clinical biochemists play a critical role in development of services and support the consultant. This role needs to be enhanced in the future to keep pace with technology developments in the discipline. Consultant clinical biochemists are heads of department and responsible for the clinical and scientific governance and strategic direction of clinical biochemistry services in many hospitals throughout Ireland, including national services. Given that clinical biochemists can progress ultimately to consultant positions, their role in the laboratory, training within scope of practice, and career pathway must reflect this.

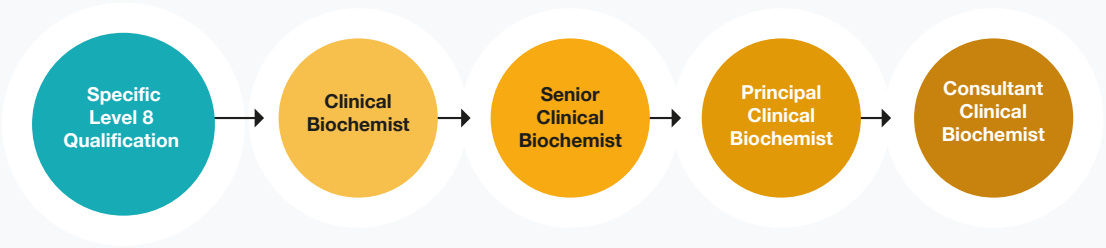


Figure 14: Clinical biochemist career pathway

Current Career Progression and Challenges

For most clinical biochemists entering the profession, there has been no dedicated training programme. Rather, they have learned on the job and progressed to more senior positions with the support of consultant clinical biochemists. To address this, in 2020, an MSc in Clinical and Diagnostic Biochemistry commenced to provide the bespoke clinical training required to undertake a career as a clinical biochemist. However, unless a clinical biochemist post becomes available upon completion of this MSc, said graduates are not guaranteed a position in the health service and seek employment elsewhere. A clinical biochemist may enter the profession with an MSc (as listed on hse.ie) however attainment of this particular MSc in Clinical and Diagnostic Biochemistry is not currently a mandatory eligibility requirement for clinical biochemist posts.

Once in the profession and with sufficient experience, clinical biochemists can apply to enter a more specialised training programme organised by the Association of Clinical Biochemists in Ireland (ACBI) which supports the career progression of clinical biochemists. It is designed to achieve the exit qualification (FRCPath by examination) and competencies required to progress to a consultant clinical biochemist position. For scientists, the FRCPath examination is regarded in the UK as an assessment of a candidate's training, indicating fitness to practice, whilst at the same time signalling the entry into independent practice. For doctors on the UK's General Medical Council's register, the FRCPath examination contributes to the award of the Certificate of Completion of Training (CCT) but does not in itself entitle the graduate to specialist registration. In Ireland, the FRCPath is not sufficient in isolation and the training that a clinical biochemist undergoes to attain the competencies required for a consultant post is critical and must be supported and regulated. Most consultant clinical biochemists practising in Ireland have completed at least some element of training in the UK.

Training of scientists to specialist level in the EU is aligned in 19 of 27 countries (as of 2020) with the EFLM (European Federation of Clinical Chemistry and Laboratory Medicine) equivalence of standards (ELFM, 2020). These equivalence of standards criteria are as follows:

- Minimum nine years (ideally 10) years academic (4/5 years) and specialist (five years) training.
- Education and training to standards set out in the EFLM syllabus for postgraduate training and education for specialists in laboratory medicine (v5 2018).
- A master's degree in medicine, pharmacy or science.
- An EFLM Profession Committee recognised 'equivalence of standards' exit qualification.
- Evidence of participation in continuous professional development (CPD).

Positive elements of the current system are:

- Once in training, individuals have a logbook of experience to complete, attend tutorials organised by the ACBI tutor, and partake in an annual assessment with a panel that includes an external assessor. Completion of all components and reaching an acceptable standard at annual assessment is required for continuation in the programme.
- The EFLM recognises the training of clinical biochemists in Ireland through the ACBI programme as meeting the equivalence of standards, thereby allowing clinical biochemists who have completed training to apply for the designation EUSpLM (European Specialist in Laboratory Medicine). This is a register of laboratory medicine specialists in the EU.

Challenges associated with this current system are:

- Training at entry level is non-standardised.
- The training programme run by the ACBI does not have any recognition or support from the HSE or Department of Health. The ACBI is a voluntary professional organisation that relies on the time of a small number of members in senior clinical biochemist positions (consultants and principal biochemists who have completed FRCPath) to support such a programme. This is not sustainable.
- Those undertaking the programme do not receive any funding or support in terms of protected study time such as would be forthcoming in the UK, other EU member states or for training medical colleagues.
- The training is not assessed and accredited by a regulator.
- Not every Biochemistry department supports this training of its Clinical Biochemist staff, resulting in Clinical Biochemists having to use annual leave to attend tutorials, or relevant training events.

- Due to current pressures in all laboratories, clinical biochemists are limited in their ability to participate in the required training opportunities.
- There is no mechanism for training in highly specialised areas of biochemistry.
- Attainment of a PhD is highly desirable for progression to a consultant post, which requires success in a competitive grant application, willingness of suitably qualified supervisors to commit to supervision, as well as employer support. As funding does not provide backfill, the project must be aligned with departmental and organisational goals. Such a system can be mutually beneficial to the health service and the candidate as projects undertaken within a clinical laboratory can contribute to service development.

The lack of national state registration for clinical biochemists means that they do not fulfil all the requirements of the proposed EU Common Training Framework for Specialists in Laboratory Medicine proposed by EFLM. In addition, they are not listed as a regulated profession under Directive 2005/36/EC on the Regulated Profession Database maintained by the EU (European Commission, 2022). The Department of Health (previously the Department of Health and Children) is the competent authority for the profession under the Directive 2005/36/EC on the free movement of professionals.

Future Considerations

The following have been identified as key issues by biochemists:

1) **A specific entry level training programme.** A proposal was previously put to the HSE to replace the basic clinical biochemist grade post with a trainee position as outlined in *Figure 15*.
2) **Specialised training pathway to Consultant.** Training of future consultant clinical biochemists should be standardised, regulated, funded, and supported. Therefore, training throughout the career of a clinical biochemist must be consistent, structured, and regulated to ensure accepted standards of training and competence are met.
3) **Specialist registration** for those who have completed higher specialised training as described later in this chapter.
4) Ensuring sufficient numbers of clinical biochemists to fulfil workforce and training needs.
5) There is a need to ensure that principal clinical biochemist roles are replaced when vacancies arise.

At entry level, high calibre life science graduates/postgraduates would undertake a proposed 3-year training programme which should include the following elements organised centrally, similar to the Scientist Training Programme (STP) in the UK for example:

- A specific number of training positions across the country annually according to workforce planning numbers.
- Competitive entry at a national level.
- Funding at a national level.
- A specific period of work-placement and experiential learning with defined learning objectives. This should be in laboratories accredited to undertake such training and with appropriate supervision, and with progress reviews.
- MSc including a research project.
- Following successful completion of certified training, registration as a clinical biochemist would occur.

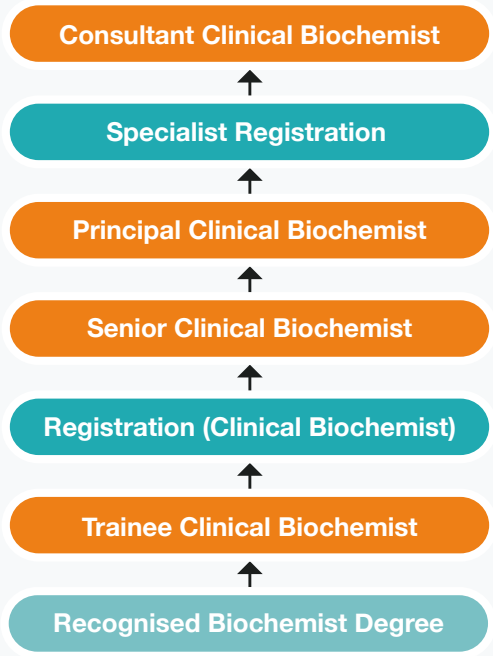


Figure 15: Proposed training pathway for clinical biochemists

The foundations of such a programme exist in Ireland. Of note, a pilot was previously undertaken at the Mater Hospital in conjunction with the ACBI in 2007, whereby a clinical biochemist undertook the STP training programme in the UK, based in Dublin. However, a lack of funding precluded any further intake.

Clinical Scientists

The majority of clinical scientists in Ireland work in the genetics and genomics field. The Irish genetic service is seriously understaffed at all levels from clinical to clerical. Despite this, current developments in the field of genetics have put a heavier emphasis on scientific and laboratory diagnostics as a mechanism for more accurate screening, diagnosis and treatment of genetic disease, hereditary cancer syndromes and cancer. These developments require that staff trained in the analysis and interpretation of complex genetic data are available from the date of inception of any new service developments. This is in addition to the training requirement for clinical, nursing, counselling, and technical staff, such as bioinformaticians, which must also develop if these technologies are to be applied in a clinical setting.

A workforce planning exercise needs to be carried out to ensure an adequate number of clinical scientists are trained to meet the forecasted requirements for the Irish genetic service when compared to a developed genetic service in a population similar to Ireland, such as NHS Scotland. Additionally, the existing headcount will continue to be a significant proportion of the clinical scientist workforce and upskilling will be necessary to ensure that staff are able to deal with the new requirements of the service.

Routes of Entry:

There is no standardised training pathway for clinical scientists in Ireland. A subset has entered the profession by completing a dedicated clinical scientist training program (internationally). Of the remainder, the majority have entered with a relevant MSc or PhD and have learned on the job through comprehensive in-house training programmes.

Current practice for entry into a clinical scientist post is most commonly one of the below:

- Clinical scientist training in the UK, Scientist Training Programme.
- Relevant PhD.
- Relevant MSc with adequate experience.
- Relevant BSc with 2-year in-house training.

Eligibility criteria to progress to promotional posts vary between labs and over time, however, from 2021 a proposed standard has been set forth by the Irish Association of Clinical Scientists (IACS) and requires consultation with HR. The proposed standards are as follows:

- **Senior Clinical Scientist:** 3+ years' experience plus MSc and FRCPath Part 1 OR PhD
- **Principal Clinical Scientist:** 5+ years' experience plus PhD and/or FRCPath
- **Chief Clinical Scientist:** 7+ years' experience plus PhD and/or FRCPath

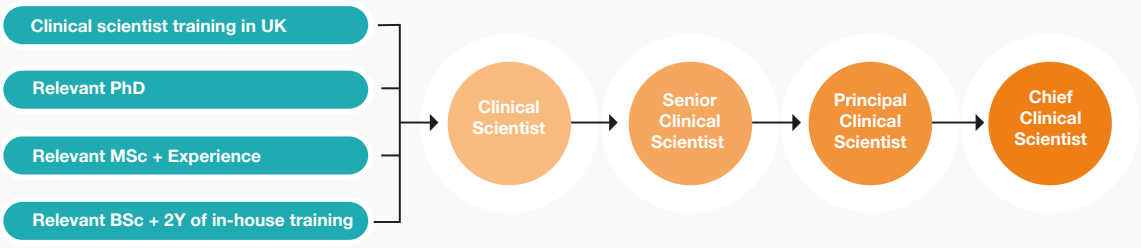


Figure 16: Clinical scientist career pathway

Current Career Progression and Challenges

The issues regarding Clinical Scientists regulation are recognised and remain to be resolved. Most Senior Clinical Scientist positions (Senior, Principal and Chief) have PhD, DipRCPath and/or FRCPath. Training and support to achieve such milestones is ad hoc in Ireland with little support available. The majority of clinical scientists have completed PhDs or FRCPath exams in their own time at their own expense.

Positive elements of the current system are:

- Despite the challenges, Ireland has developed a highly skilled workforce of clinical scientists.
- Flexibility exists within the current process to recruit scientists with diverse skills to meet new service demands (e.g., molecular genetics, bioinformatics).
- Flexibility to adjust 'in-house' training to provide new and emerging diagnostic tests.

Challenges associated with this current system are:

- Clinical scientists are not recognised as a HSE grade.
- Clinical scientists are not eligible to register with CORU.
- There are not enough trained clinical scientists in Ireland to meet the service demand.
- There is no structured training programme, therefore the burden and expense of training falls on the diagnostic laboratory while trying to maintain business as usual. Training is largely apprenticeship-style, with trainees contributing to service development and delivery, however staffing needs to be sufficient to allow time for both trainee and trainer participation in the full range of relevant training activities.
- As clinical scientists are not a recognised profession, career progression is challenging with few avenues to facilitate further study/development.
- Due to workload pressures, it is difficult for clinical scientists to keep pace with the rapid advances in genomics and genetics

The creation of clinical scientist posts in cytogenetics and molecular genetics was recommended as part of the Tierney report "Committee to Examine Medical Genetics Services", published in 1990 (Tierney, 1990). Despite being an integral part of the service and employed by the health service for 30 years, this is still not an officially recognised HSE grade and thus clinical scientists are currently only classified as an aspirant profession by CORU which complicates registration.

Future Considerations

The following have been identified as key issues by clinical scientists:

1) Clinical scientists are not recognised as a HSE grade. The issue surrounding clinical scientists recognition is recognised and remains to be addressed. Recognition would allow the distinct role to be clearly defined as well as the specific entry requirements for the profession, which would greatly increase recruitment and retention.
2) Progression from aspirant profession to registered profession with CORU.
3) A dedicated training programme for clinical scientists should be established. Entry should be competitive into a formal training programme with an interview process requiring at minimum a BSc in a relevant discipline. A similar approach is in place for medical physicists which can be found here. This programme would ideally consist of:
    - Two-year apprentice style training programme, including a MSc plus experience as a pre-registered clinical scientist.
    - It is anticipated that pre-registration placement experience would be gained through a rotational programme of relevant sub-specialties within the specified discipline. This would be supervised to ensure the clinical scientist gained the appropriate competencies, requiring a portfolio of evidence to demonstrate said competencies required for registration.
4) Clinical scientist have a distinct role and competency, and the issues regarding their regulation are recognised and remain to be resolved. Development of specialist registration for clinical scientists practicing autonomously should be explored.
5) There is a need for a specialised training on a career pathway towards autonomous practice, with further discussion on terminology and scope of practice required.
6) Training of sufficient numbers of clinical scientists to meet current and future service needs.
7) A comprehensive continuing professional development system should be considered to ensure clinical scientists keep abreast of the most recent advances in genomic medicine.

Figure 17 demonstrates a proposed career structure for clinical scientists:

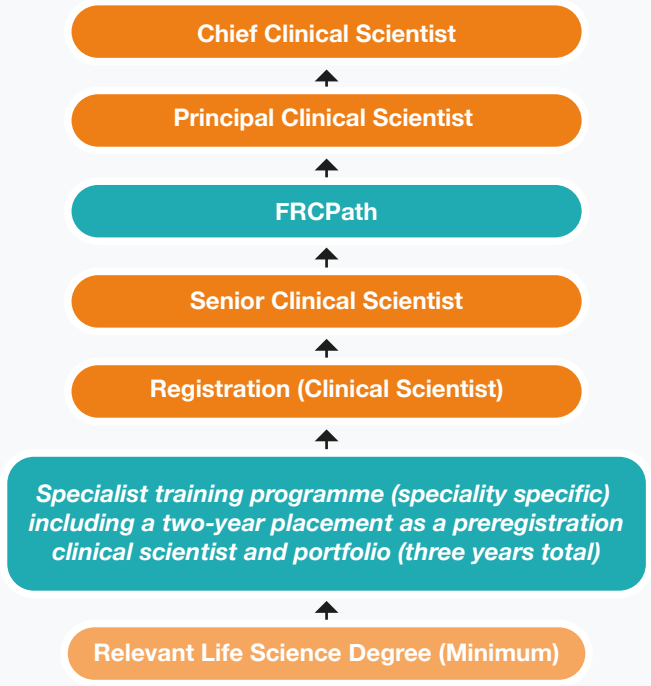


Figure 17: Proposed training pathway for clinical scientist

Medical Scientists

Routes of Entry:

Medical scientists are employed across all specialties and subspecialties of clinical diagnostic laboratories across the Irish health service as medical scientists, senior medical scientists, specialist medical scientists, and chief medical scientists, as well as those working as laboratory managers. In addition to these traditional roles many are employed within laboratories as quality officers, it scientists, surveillance scientists, haemovigilance officers or point of care coordinators. Their remit extends greatly beyond the analysis and timely reporting of results and examples of other responsibilities include:

- Participation in MDTs for services such as haematology and oncology.
- Participation in transfusion and hemovigilance committees.
- Participation in antibiotic stewardship committees.
- Participation in hospital infection control teams if employed in the role of a surveillance scientist.
- Involvement in local, regional, and national committees.

Entry to the profession requires eligibility for registration with the Medical Scientists Registration Board of CORU. Qualifications and additional requirements are detailed here. CORU requires that registrants attain the standards of proficiency as prescribed by the registration board. The standard route of entry is via one of the approved programmes as laid down in bye laws. Such programmes are level 8-degree qualifications in biomedical science/medical science with modules in general science and in each of the major specialties of laboratory medicine, the pathogenesis of disease and a research thesis. All approved programmes include a clinical placement in each of the major specialties.

Eligibility to progress is as follows:

- **Senior Medical Scientist:** MSc and four years' experience in a clinical diagnostic laboratory since qualifying as a medical scientist
- **Specialist Medical Scientist:** MSc and four years' experience in a clinical diagnostic laboratory since qualifying as a medical scientist plus knowledge and experience in the specialism
- **Chief Medical Scientist:** MSc and seven years' experience in a clinical diagnostic laboratory since qualifying as a medical scientist, two of which were as a senior or specialist
- **Laboratory Manager:** MSc and seven years' experience in a clinical diagnostic laboratory since qualifying as a medical scientist, two of which were as a senior or specialist

All registration and progression requires evidence of continuing professional development.

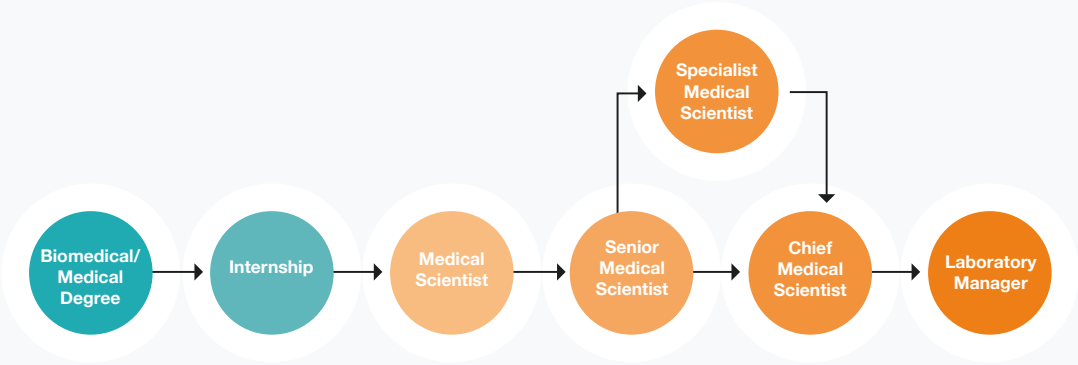


Figure 18: Medical scientist career pathway

Current Career Progression and Challenges

The standard route into the profession is clearly defined and is configured to ensure that the medical scientists entering the clinical diagnostic laboratory have the knowledge, skills and competence required. These competencies include but are not limited to undertaking analysis, participating in pre-analytical and post-analytical phases of the service and may include interpretation of results. The current number of students accepted onto programmes is limited by the number of approved clinical training positions. However, a combination of a lack of workforce planning and graduates pursuing alternative careers has led to a critical and chronic shortage of suitable candidates to fill posts. Moreover, the rigorous training provided makes graduates attractive to private sector organisations such as pharma and the in vitro diagnostics industry. As a result, in 2021 only 35 of 115 graduates embarked upon a career within the health service. Moving forwards, consideration must be given to identifying the factors motivating individuals to leave, in order to determine what may facilitate retainment of staff. This should occur irrespective of the recent increase in undergraduate medical science students.

In the current system, there is ready access to approved MSc programmes which are mandated for progression to the senior medical scientist position. There is no agreed funding or protected time for such participation. However, the absence of a structured training programme towards higher specialist training, professional doctorates or FRCPath prevents greater numbers of medical scientists from acquiring the further knowledge and expertise valuable for some advanced practice. Consequently, many have had to attain such qualifications without any formal structures or support. Consultant clinical biochemist positions are available in some biochemistry laboratories. The lack of a senior level role leading to autonomous practice in all other disciplines, along with the structured training to develop the medical scientist to undertake such a position is both limiting on the provision of the clinical diagnostic services and equity of career progression for medical scientists. This disparity has been a source of conflict within the clinical diagnostic laboratory service.

Medical scientists with MSc and four years' post qualification experience are eligible to apply for Fellowship of the Academy of Clinical Science and Laboratory Medicine.

Positive elements of the current system are:

- Medical scientists, upon graduation and registration are eligible to practice in all major specialties in the clinical diagnostic laboratory owing to the multi-disciplinary nature of their training. The multidisciplinary clinical placements provide exposure and experience in a wide range of analytical techniques ranging from automated technologies to those that rely on individual skill and competence.
- They can partake in routine and 'out of hours' services in either a single specialty or multidisciplinary as required.
- The flexibility of the medical scientist workforce became apparent when there was a need to scale up molecular-based testing for COVID-19. To provide this service on a 24/7 basis medical scientists from all areas of the laboratory could be, and were, redeployed to do this work.
- Most laboratories, although not contractually obliged, provide a 24/7 service for urgent analysis. In many hospitals provision of this service is possible as medical scientists use their diverse skills covering biochemistry, haematology, microbiology, and transfusion science cover outside routine hours.
- Notwithstanding the lack of a structured higher specialist training programme a small number of medical scientists have attained such higher specialist training and are eligible to apply for the designation EUSpLM (European Specialist in Laboratory Medicine).

Challenges associated with the current system are:

- A significant proportion of graduates do not enter the clinical diagnostic laboratory workforce, which has contributed to the current severe staff shortage.
- The standard clinical placement programme does not serve the needs of subspecialties. It concentrates on anatomical pathology, clinical biochemistry, haematology, microbiology and transfusion science leaving areas such as immunology, toxicology, virology, h&i, bioinformatics, genetics and genomics etc., and other emerging areas for post graduate training. This can lead to recruitment difficulties in these areas, as many medical scientists have not been exposed to the subspecialty and may not therefore choose to work in that area on qualification. To address this deficit a reconfiguration of the clinical placement programme by extending its length or by permitting students to choose some subspecialty could be considered.
- Participation in CPD is mandated to remain on the medical scientists register. Such CPD is self-directed based on practice setting. While professional bodies provide opportunities for CPD there is no formal allocation of time or support to maintain this portfolio
- There is no structured training programme to develop the scientists to higher specialist and help meet the evolving needs of the health service. Not every clinical laboratory supports the training of its medical scientists staff, resulting in medical scientists having to use annual leave to attend tutorials or relevant training events. Where training is delivered in-house, a heavy burden is placed on small volumes of staff to deliver training and services.
- The majority of medical scientists who attain higher qualifications such as PhD do so outside the clinical diagnostic laboratory service. Attainment of a PhD should be seen as mutually beneficial to the health service and the candidate as projects undertaken within a clinical laboratory can contribute to service development.
- Some medical scientists study to undertake the FRCPath exam but like the other professions, training and support to achieve such milestones is ad hoc in Ireland with only local or professional body support available. Medical scientists with this qualification are also registered as clinical/biomedical scientists with the Health and Care Professions Council (HCPC) UK.
- Measures should be considered to attract scientists who have undertaken PhDs or other relevant experience to re-enter diagnostic laboratories with recognition of gained competencies.
- The number of senior/promotional posts is insufficient, which may act as a barrier to staff development and in turn retention.

Future Considerations

The following have been identified as key issues by medical scientists:

1) To increase the pool of medical scientists, a CORU approved post graduate entry route (with sufficient capacity) is required for candidates with relevant life science degrees to gain the academic knowledge and training to register as a medical scientist. For this to be valuable consideration needs to be given to funding supports and for programme approval to occur at the earliest opportunity.
2) The configuration of clinical diagnostic laboratories varies across the HSE hospital models. The Model 2 hospitals may benefit more from a multidisciplinary enabled scientists while Model 4 hospitals are likely to benefit more from scientists with depth of knowledge and experience in a narrower area. Training must appreciate this and be configured to meet such diverse needs.
3) A mechanism is required to attract back into the clinical diagnostic laboratory those who have taken time out for personal reasons or to pursue further qualifications. Increased opportunities should be in place for those who wish to work less than full time.
4) There should be a structured training to develop skills to be eligible for the chief/specialist medical scientist positions. Training should be a continuum.
5) Attainment of a PhD and/or FRCPath should be seen as beneficial to the health service and structured training pathways and supports should be put in place to facilitate such training. Chief medical scientists and specialist medical scientists should be supported to complete a PhD, professional doctorate and/or FRCPath.
6) Along with other scientific colleagues there is a need for a specialised training on a career pathway to autonomous practice, with further discussion on terminology and scope of practice required. These roles are necessary for the strategic development of all specialities and subspecialties within the clinical diagnostic laboratories and for the development of national services.
7) The current regulation model of CORU registers professionals upon entry into the profession. The policy is that registrants operate within their scope of practice. To meet the needs of clinical diagnostic laboratories, the health service and to ensure protection of the public, a regulation model that recognises levels of competence should be considered similar to that of the Medical Council.
8) To align the career structure with other scientific grades, the years' experience for senior medical scientist should be modified to three years post qualification with a further two years in a promotional position for chief medical scientist.
9) Consideration needs to be given to the appropriate ongoing management and scientific training of chief medical scientists and laboratory managers. Support should be available to pursue further training such as a Professional Doctorate, a PhD or the FRC Path.
10) Development and enhancement of structured support grades to assist the medical scientists and other scientists working in our clinical diagnostic laboratories. This will allow such support grades to undertake the more repetitive tasks, freeing up the medical scientists to undertake more complex roles, research, and development for which they are trained. Maximising the potential of the medical scientists is thought to be key in improving staff retention.

Figure 19 demonstrates a proposed career structure to maximise the potential of medical scientists.

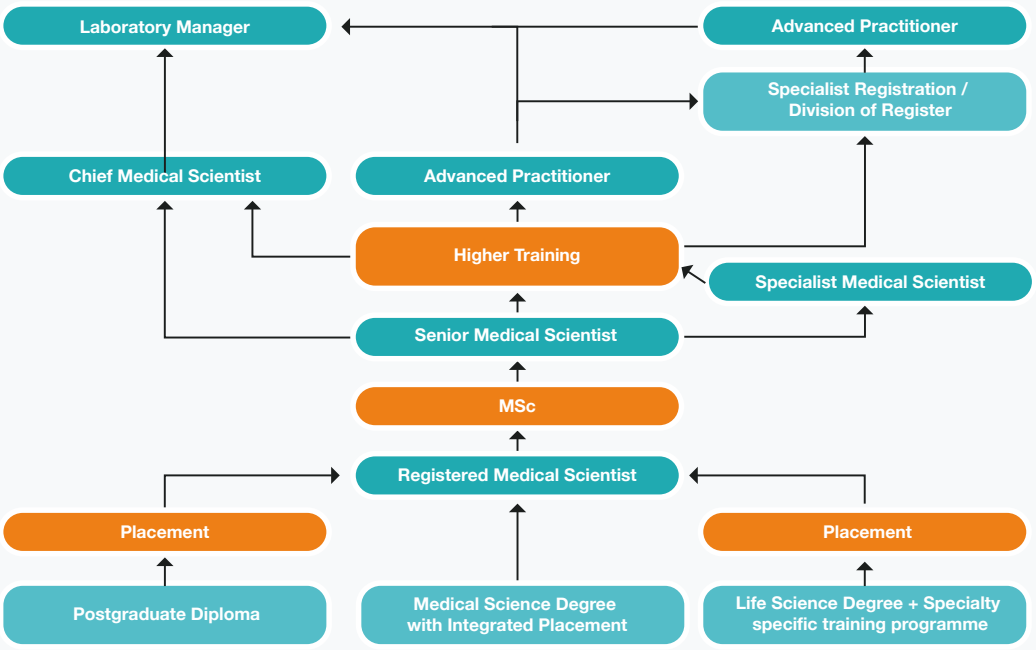


Figure 19: Proposed training pathway for medical scientists

Laboratory Managers

Given the pivotal leadership role of the laboratory manager, it is important that due consideration be given to their post graduate education and training needs. While organisations have HR, finance, and procurement departments the laboratory manager must be able to ensure recruitment, training and mentoring of staff. They must be equipped to manage conflict, adhere to procurement guidelines, and have a comprehensive understanding of quality management and risk.

Previous editions of the laboratory manager job description stipulated a significant management qualification. Many laboratory mangers hold the MBA in Healthcare Management, whilst others have little or no formal management training.

Support must be given to scientists to attain the necessary management education and training to take this important operational role. The lack of such training makes recruitment to this role difficult. Professional Doctorates may have modules that would address this deficit.

Laboratory Aides and Technologists

Laboratory Aides

Laboratory aides are a group of support staff employed in clinical diagnostic laboratories. They perform many essential pre analytical tasks in all departments. There is no agreed job description or route for career progression. The important contribution they make to the service was recognised in their recent pay award.

As the work in clinical laboratories becomes both more automated and more complex the role and contribution of laboratory aides becomes more important. Delegating the appropriate tasks can allow laboratory aides to develop skills and competencies, while scientific grades focus on other activities aligned with their training.

In the majority of laboratories, the critical pre analytical area of specimen reception is staffed by laboratory aides. This process requires the careful checking of specimen to request allocation of a laboratory accession number for tracking of the specimen through all processes and in the absence of order communications, registration of the specimen in the LIMS. Samples are then brought to the analytical area for testing.

Additional roles which can be allocated to laboratory aides, either now or in the future include but are not limited to:

- In automated blood sciences areas loading of samples and reagents on analysers
- Referral of samples to external centres for analysis
- Reconciling referred tests
- Stock control
- In microbiology laboratories primary inoculation of samples onto culture media
- In histopathology assisting in gross examination of specimens
- In histopathology learning the manual skill of microtomy
- Similar roles can be devolved in many other areas of the laboratory.

There is no agreed entry level qualification nor 'in post' training. Along with all staff in laboratories laboratory aides require education and training in quality processes and health and safety procedures.

The supervision of laboratory aides is frequently an issue. As there is a need for a career structure for scientists so there is a need for formal education training and career structure for laboratory aides. Similar to programmes for healthcare assistants there should be programmes developed to credential laboratory aides. The development of a senior support grade could be an advantage and such staff may wish to progress to the post graduate entry route to be a registered scientist.

Genetic/Molecular Technologists

Genetic/molecular technologists perform a range of molecular and cytogenetic techniques and use a range of technologies related to genetic analysis. They are predominately involved in the laboratory processing of samples in genetic molecular pathology labs. They are an essential staff member in a genetic/molecular pathology laboratory. The entry requirement is a BSc in a relevant subject (genetics/biology). Genetic technologists are not listed on the current HSE directory of staff grades. Further work is needed to align the general laboratory grade structures as highlighted with that of the Laboratory Strategic Workforce Plan. There is currently no formal training programme for genetic technologists in Ireland. Such a grade may be valuable in many other disciplines, and the development of this should not be restricted to genetics and genomic laboratories.

The European Board of Medical Genetics (EBMG) is developing standards and registration for Laboratory Genomic Technicians.

Anatomical Pathology Technicians

APTs assist in performance of post-mortems and subsequent preparation of body for viewing and burial. There are no formal courses available in the state and APTs learn 'on the job' and undertake the Royal Society of Public Health training and diploma examinations. With the expected publication of the Human Tissues Bill, it is likely that the role and responsibility of this grade will change.

Future Career Development Opportunities

The advent of advanced roles for scientists should be seen as an opportunity to develop the clinical diagnostic laboratory service rather than a threat to existing structures. The terminology for these roles is yet to be agreed upon and will need further discussion.

Advanced clinical practice is delivered by experienced, registered health and social care practitioners. It is a level of practice characterised by a high degree of autonomy and complex decision making. This is underpinned by a minimum NFQ level 9 award or equivalent, evidence of learning that encompasses the four pillars of: (i) clinical practice (ii) leadership and management (iii) education and facilitation of clinical learning and (iv) evidence, research, and development; and leads to the demonstration of core capabilities and area-specific competence relevant to scope of practice and role.

Advanced clinical practice embodies the ability to manage clinical care in partnership with individuals, patients/service users, families and carers and other healthcare professionals. It includes the analysis and synthesis of complex problems across a range of settings, enabling innovative solutions to enhance people's experience and improve outcomes. The *'HSCP Advanced Practice Framework'* outlines the agreed definitions, pillars, and competencies for Advanced Practice for Health and Social Care Professionals in Ireland. (HSE, 2023)

The range of analysis provided by clinical laboratories has become both more automated and also more complex. Techniques that were purely research are now being incorporated into routine practice. Advanced practitioners could be deployed to coordinate these new services. Intra and extra cellular markers are being identified, mass spectrometry can now be added to automated lines as can molecular analysis modules. Cell free DNA technology can be used to identify genetic anomalies in a fetus in addition to monitoring the progression of tumour growth. In microbiology the advent of molecular methods and MALDI-TOF has revolutionised the identification of microbes. In major haemorrhage, the introduction of thromboelastometry (real time coagulation monitoring) has revolutionised the management of the provision of blood and blood products by medical scientists. The introduction of new therapeutic drugs for both oncology and haematology patients has led to additional complexity of drug monitoring and interpretation of routine analysis. Techniques such as flow cytometry require a specific expertise in addition to an understanding of the clinical implications of the analysis. Within anatomical pathology the role of histodissection, previously the preserve of histopathologists, is being undertaken by appropriately trained medical scientists. In the UK this has advanced further to the role of collaborative reporting specific tissue types. Development of advanced career pathways will require collaboration with all stakeholders and role mapping.

The advent of sophisticated near-patient testing technologies has, and will, revolutionise primary care. These technologies can be available both within primary care centres and also for patient self-monitoring. Consultation with laboratory scientists is recommended in Irish NPT guidelines to ensure that these tests are used appropriately and with the appropriate quality assurance. Within a healthcare network the availability of advanced scientific practitioners to coordinate this service would be an advantage.

Clinical biochemistry laboratories are led by consultant clinical biochemists and/or consultant chemical pathologists. Scientists in other departments also lead innovation and bring their scientific rigour to their areas of specialty. To date they do not have a career pathway to the grade similar to consultant clinical biochemist. This is a topic for future discussion as we consider the development of laboratory medicine over the next decade.

It is recognised that, in addition to recruitment, there is a retention crisis within our clinical laboratories. In order to retain our committed scientists to contribute to excellence in patient care we need clear pathways to advanced practice and beyond in all areas of the clinical laboratory service.

Services to Support Training Requirements for Scientists in Clinical Laboratories

Support Requirements

Support requirements need to be considered at every stage of a training and education pathway. This training should be conducted in training laboratories approved by the regulator. The three key components for training can be split as follows:

1) Support Staff
2) Pre-Registration Clinical Placement Training
3) Post-Registration Training:
    a. Early career
    b. Specialism/Advanced practice
    c. Laboratory manager
    d. Consultant/Senior role leading to autonomous practice (terminology not yet agreed)

1) Support Staff Training Approval

Training laboratory support staff through an approved certificate of achievement.

2) Pre-Registration Clinical Placement Training

Training co-ordinators should have oversight over a group of trainees on clinical placement across a number of organisations to ensure standardisation.

3) Post-Registration Training

In early career this could take the form of CPD, level 9 or higher qualifications required for promotional positions.

This could then lead on to training qualified scientists in specialist areas through appropriate training programmes, being cognisant of developments in the field of advanced practice. This is aimed at senior members of the scientific professions with the ability and opportunity to undertake some specialist roles.

Scientists on a pathway to specialism will have particular resource and support requirements including training officer/supervisor with overall responsibility for supporting the candidate throughout their training. They will seek to ensure that the conditions are in place to enable the candidate to be successful and have a good training experience. This could be in the form of educational supervision including supporting the development and management of a training plan, mentoring and pastoral support, facilitation – providing access to training opportunities including rotations, assessment, and feedback. In addition to supervised training in the hospital, the candidate would be required to attend a number of mandatory courses, that help the candidate to develop professionally and acquire the non-clinical skills and knowledge needed to provide excellent patient care.

General Resource Requirements

- **People:** To facilitate a supervised training programme, appropriate individuals in the forms of educational and technical supervisors should be considered. Moreover, training posts should have sufficient dedicated time for training with appropriately appointed staff to deliver it. In order to ensure attainment of competencies, an appraisal process conducted by the training body should be incorporated into practice. There also needs to be sufficient resource within the department to allow dedicated training time.

- **Resources:** Scientists will require access to appropriate equipment and training space. Additionally financial resources will be required to provide a study budget to allow attendance at courses and conferences relevant to their practice.
- **Certification:** Scientists should be required to undertake an online portfolio demonstrating appropriate competence within their field of practice. Furthermore, individuals attending courses should be provided with appropriate CPD/accreditation similar to those conducted in clinical practice.
- **Rotation:** Provisions should be in place to allow rotation as necessary to provide individuals with experience of practice in different settings. Variations in environment may be based on laboratory size or specialisms. Specific training in specialist laboratory services needs to be included for scientists who wish to pursue a career in those areas.
- **Selection:** National or regional competitive selection process with defined criteria for appointment.

Higher Specialist Training

The aim of discipline specific specialist training is to provide the trainee with the skills and competencies required to be eligible for independent practice where appropriate and within scope of practice. The training is aimed to bring scientists from all professions beyond advanced practice. The overarching principles of such a training programme are outlined below.

1) The number of specialist training places for each discipline should reflect future workforce requirements taking account of Sláintecare priorities, which will require increased scientific governance in Model 2 and 3 hospital laboratories.
2) The training programme should be centrally organised, operated, and funded.
3) Eligibility criteria in terms of the years of professional experience and qualifications required to enter into such training must be defined.
4) Entry onto such a programme must be competitive in nature and organised on a regional/national level.
5) Once accepted into the programme, the trainees must be assigned to an approved training laboratory, under supervision of a supervisor who is typically a consultant with relevant experience and sufficient protected time.
6) Whilst the exact content is still to be defined, at a high level it must include:
    a. Workplace-based assessment of defined competencies and standards of proficiency (scientific, clinical, professional, management, audit and quality improvement, and ethics) with a log to be maintained to provide evidence of attainment.
    b. A component of academic learning to cover core competencies.
    c. Sub-speciality training needs to be incorporated (as per workforce planning). This may include a period of time spent in a specialist service in Ireland or abroad. An example for clinical biochemistry would be sub-specialisation in toxicology or biochemical genetics. Similarly in maternity settings a sub specialisation of pre-natal science may be appropriate.
    d. Minimum time served which in comparative countries, is approximately 5-years.

- Regular progression reviews must be incorporated into the programme, the aim of which would be to ensure the trainee is attaining the required competencies within the designated timeframe, and to allow the trainee to allow bidirectional feedback regarding the training provided.
- Completion of an exit examination (e.g., FRCPath) will be required, but is not sufficient, to achieve certification of specialist training.
- Once the training competencies and exit examination have been completed satisfactorily, a certificate of completion will be awarded. This would allow the trainee to register as a specialist.

Professional Regulation of Scientists

Registration underpins effective regulation. The regulators roles include:

- Registration of the individual practitioner.
- Regulation of training, assessment, and certification.
- Oversight of on-going CPD.
- Fitness to practice assessment and procedures.
- Addressing complaints from patients, healthcare providers, and healthcare organisations.

Regulation requires registrants to comply with appropriate codes of professional practice. A standard requirement in CORU's Codes of Professional Practice and Ethics is that registrants must "act within the limits of your knowledge, skills, competence and experience" and "practise only in areas in which you have relevant knowledge, skills, competence, experience, or are appropriately supervised".

Medical staff in clinical diagnostic laboratories are regulated by the Irish Medical Council. Medical consultants are on the specialist register in a designated specialty and trainees are on the trainee register.

Medical scientists are subject to regulation by CORU, Ireland's multi-profession health regulator. There are two primary structures of CORU:

a) **Council:** Overseeing registration boards, assessing fitness to practice, and corporate functions.

b) **Registration Boards:** Registration, education, and continuing professional development.

Within the realm of laboratory medicine, registers only currently exist for medical scientists. The function of the board is to create bye laws governing their registration as scientists, maintaining the register, and approving said education and training. Moreover, this board is responsible for the assessment of qualifications obtained outside of the State, defining ethical conduct, guiding CPD, and implementing sanctions for fitness to practice where relevant.

A register for clinical biochemists is mandated under the 2005 Health and Care Professions Act, however the profession remains in the pre-establishment phase awaiting appointment of a registration board by the Minister for Health.

Clinical scientists are not named in the Act. They are currently an aspirant group for registration.

The purpose of regulation is to protect the public. This is done by promoting high standards of professional conduct, education, training, and competence through statutory registration. Registrants are expected to maintain their competence through continuous professional development. Regulators have the power to investigate complaints made against registrants, to make findings and to issue sanction.

Both the Irish Medical Council and CORU have lay members on their councils and committees. CORU, being a multi-professional regulator has one member of each regulated profession on its council. The operation of its regulation seeks to find a single model which applies across all professions. However, this model has limitations due to its inability to recognise some important nuances particular to each of the professions it regulates. Regulation is confined to the entry level to a profession and is predicated on each candidate meeting all of the standards of proficiency. Approved programmes must demonstrate how their graduates meet each of these standards. The standards of proficiency have generic domains for all professions in addition to specific domains for the specific register. Registrants are expected to operate within their scope of practice.

Positive elements of the current system are:

- Medical scientists, on graduation from approved programmes are eligible for registration are capable of practice in all major specialties in the clinical diagnostic laboratory.
- There is a clear and transparent process for application to join the register for candidates who have not graduated from approved programmes
- Each candidate's application is compared with the standards of proficiency and where deficits are identified a period of adaptation is suggested to address these or the candidate may choose to undertake a competency examination.

Challenges associated with the current system are:

- Medical scientists are the only scientific profession registered and it is unclear when the register for clinical biochemists will be opened, and if a register for clinical scientists will be added. This is not equitable.
- Consultant clinical biochemists are not regulated in this jurisdiction, being registered in the UK. Following the implementation of Brexit, the UK has withdrawn from the Internal Market Information (IMI) System, thus registered complaints may not be communicated to Irish authorities.
- The existing system for medical scientists is not sufficiently agile to accommodate candidates who have the necessary academic education without the multidisciplinary practice training to meet all the standards of proficiency. Such scientists may have several years' experience in a single discipline in another country but to register in Ireland must undertake a period of adaptation.
- The initial assessment of competence is administrative with verification from other regulators. Within the EU the IMI System provides a level of assurance of standard which may not be available globally. An additional challenge is the assessment of scope of practice, and the level of that practice, compared with that of scientists in Ireland.

Future Considerations

To address the identified challenges and to support the strategic development of clinical diagnostic laboratories a number of issues need to be considered:

- All scientists working in clinical diagnostic laboratories must be subject to regulation.
- The regulatory process must be sufficiently agile to acknowledge and accommodate the diversity of education, training, and specialty of its registrants.
- The entry level to the existing register is that of a level 8 BSc. There is no recognition of the additional postgraduate education and training of scientists and their move towards advanced practice.
- On examination of the register, it must be clear to employers and to the public the expected standard of practice to which the registrant should be held.
- The configuration of regulation needs to be able to accommodate
  - Trainee level/Pre-Registration
  - Entry level with specialty designation
  - Advanced/Specialist level with speciality designation
- Such a configuration would define the education and training for each level of the register along with the necessary competences to hold a specialty designation and permit more than one such specialty.
- Such a configuration would have the agility to designate additional specialties as required for public safety.

While the proposal above may require legislative change its application across all the professions, as required, would support the introduction of advanced practice across all regulated professions. The existing Act does permit the Council of CORU to make divisions of the register of its own volition.

Summary of Key Considerations

Consensus Agreement

1) Immediate actions required to maintain the current service

In the face of increasing demand, and urgency in catching up on care delayed by COVID, laboratories are experiencing a severe staffing crisis with an unsustainable level of vacancies, which is already leading to reduced level of service, increased out-sourcing and delayed turnaround times. To stabilise the current service the following urgent actions are required, as described in the introductory section:

- Order communications.
- Expanding MLA numbers and roles, together with development of a career structure.
- Additional staff undertaking a level of analytical tasks.
- Engagement with CORU and the Department of Health to review registration requirements.
- Adequate clerical and administrative support.
- An immediate evaluation of ICT systems with a feasibility study being undertaken.
- Support for additional automation where appropriate.

In 2021, only 35 of 115 Medical Science graduates embarked upon a career within the health service. It is imperative moving forward that those leaving are invited to complete a survey to help identify graduates motivating factors, thus providing insight into what can be done to attract them to a career in laboratory medicine.

2) Structured entry routes at all levels

There should be defined criteria for entry into all professions, including structured training. In addition, there should be postgraduate entry routes for candidates to gain the academic knowledge and training to register in their chosen profession.

A national workforce planning exercise should be undertaken to establish current and future need for the different professions, to inform intake to the current and future programmes and to ensure that the number of places within such routes of entry should be aligned with service requirements.

3) Development of advanced practice roles

Advanced practice roles need to be developed including structured training.

4) Structured higher specialist training programmes

A structured higher specialist training programme is required for roles beyond advanced practice. Given that clinical biochemists operate in consultant roles, this needs to be implemented as a priority for this group. It should be regulated, supervised, validated, and assessed to ensure required outcomes are achieved with individuals being assessed on competency, including clinical/laboratory skills.

5) Registration and regulation

It is recommended that all scientific professions operating within HSE laboratories are recognised as health and social care professionals and have registration boards to ensure they are operating in a regulated environment. Registration boards not already established should be facilitated as a priority.

6) Specialist registration

Where any level of independent practice is considered, this must be underpinned by specialist registration within the jurisdiction.

7) Training support for specialist laboratories

Given the specific expertise required by specialist laboratory services support is needed to train, retain, and develop relevant laboratory professions for these services.

8) CORU approval for postgraduate courses leading to registration

CORU should be requested to continue to provide approval for new postgraduate courses leading to registration. Otherwise, there may be a reluctance of students to enrol until full approval is in place, delaying training of much-needed scientists

9) Increased accessibility to doctorate level training and research

Improve the engagement with funding bodies and employers to facilitate this on a full or part-time basis

10) Recognition of clinical scientists as a HSE grade

Clinical scientists need to be recognised as a HSE grade.

Reviews and Updates

The progression and implementation of these considerations should be processed with some urgency and should be reviewed at least every five years.

Further discussions required

1) Role of scientists beyond advanced practice

There is a need to map roles for scientists beyond advanced practice to prepare the service for the future. There is some concern surrounding the expansion of the terminology “Consultant” to other grades.

2) Single spine structure for scientific grades

There was insufficient time to explore the feasibility, pros, and cons of a single spine structure. We recommend that further discussion with all stakeholders is undertaken as to how this might be progressed. The qualifications and experience required to progress to senior roles and beyond should be harmonised across the professions.

3) Expansion of genetic/molecular technologist role to other disciplines

Such a grade could be valuable in many other disciplines, and perhaps the development of this grade should not be restricted to genetics and genomics laboratories, however further discussion is required.

Requirement for an Integrated Plan

Integrated Approach

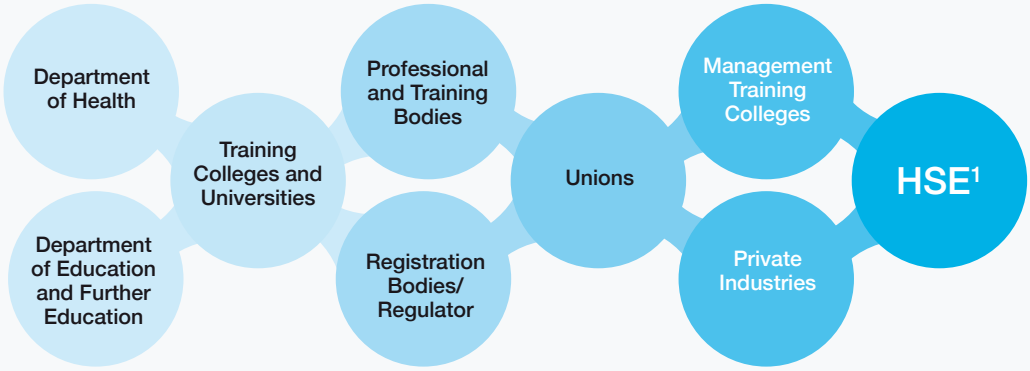
It is clear within this review process that many recruitment and educational difficulties exist within the health service, particularly related to a number of key disciplines. At the same time, there exists significant potential and opportunity to address both the short- and longer-term issues across laboratory medicine using a systematic approach involving collaboration between key stakeholders.

To address and improve the current and future planning approaches, it would be necessary to establish an integrated implementation group with a specific remit and role to focus on the education, training, and career development of laboratory staff. In broad outline, the HSE proposes that such an integrated implementation group would have the following objectives:

1. The service is provided by a multi-professional team and therefore requires collaborative role mapping which will inform the development of the necessary education pathways, assessment of competencies, and definition of care pathways which are a pre-requisite for patient safety.
2. Develop for laboratories an overall education, training and professional/career development plan agreed by all strategic partners. This would include the required retention strategies relevant to increasing recruitment into laboratory-related careers, promoting, and supporting the advancement of staff within a defined career structure and reducing turnover rates.
3. Based on solid workforce planning requirements specify, the future laboratory staffing numbers factoring in, skills requirements, technological changes, training requirements and other relevant capabilities. It is likely that this approach could encompass both the public and private sector needs to maximise the health service and broader scientific needs of Ireland.
4. Develop an implementation of the plan of the recommendations, noting that some areas can be achieved in a short time period.

This integrated implementation group should have a defined mandate to progress the issues of relevance with clear and agreed responsibilities for implementation delineated. The development of any training and education plan should include a future commitment to its resourcing to ensure its effective implementation.

This review recommends the participation of the following key stakeholders as part of the integrated implementation group:



1: HPSC Programme | Clinical Programmes | Hospitals | Human Resources | NDTP | National HSCP Office

Section 3.0

Review of scientific and technologically enabled advances in laboratory medicine.

Introduction

Background and Context

Technological and scientific advancements have the potential to significantly impact laboratory medicine in Ireland. Not only are they essential in improving techniques currently employed, but they are also vital in meeting future demand. For this reason, laboratories must keep pace with these advancements. This section of the report will analyse the future technological needs of laboratories through a variety of lenses – the approach taken is described below.

Approach

In recent years, there has been a substantial increase in the number, range, and functionality of technologies available in laboratory medicine. Therefore, a strategic approach was taken to ensure that a) technologies were appropriately considered and that, b) key technologies were included within the report. As a first activity, a matrix was developed to facilitate the assessment and critical appraisal of technologies. It describes seven different areas against which technologies were assessed. These include:

1. Clinical and Service Need
2. Technology and Infrastructure
3. Human Resource
4. Clinical Governance
5. Overarching Cost/Benefit
6. Implementation Consideration
7. National/International Examples

The matrix was central to the research conducted by the group and was deployed in the following situations:

Phase 1

The matrix was used by members of the workstream to critically appraise and assess technologies deemed important by the group.

Phase 2

The underlying structure and themes of the matrix were used to construct a survey that was disseminated to all laboratory staff nationwide, via professional bodies and respective laboratory managers. The survey was open between 06/06/2022 and 01/09/2022 with the logic of obtaining information on future technologies from the wider community of scientific staff. Their familiarity with the reported technologies varied – some individuals had direct experience whilst others were aware of the technologies through study and literature.

Phase 3

Information was sought from 'experts' across scientific practice to gather further intelligence on specific technologies included within this report. Individuals were selected owing to recognition within the community as experts in their respective fields. The objective was to ensure both wider participation as garnered in Phase 2, coupled with specific specialist knowledge.

Data gathered across the three phases was amalgamated to produce a considered and consolidated view on key future technologies for Irish hospital laboratories. From this, **eight inter-related technologies and advances in scientific practice** were deemed crucial for Irish hospital laboratories to meet future demands. These are summarised in *Figure 20*. In-depth analyses of the below technologies against the matrix are included in the Appendices.

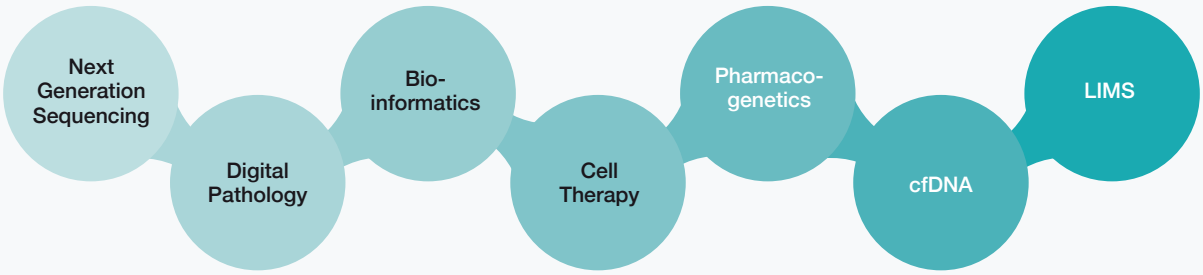


Figure 20: Technologies and scientific practices deemed crucial to the future of acute hospital laboratories

Future Aspects of Laboratory Medicine

Future Considerations for Laboratory Medicine

Ferraro *et al* (De Gruyter, 2015) in their article titled *"Laboratory Medicine in the New Healthcare Environment"* explain that many of the current changes in the healthcare environment will severely impact laboratory medicine. These include changes in demography, population ageing, patient expectations (and the new era of the *"informed/expert"* patient), chronic disease growth, movement of clinical practice to prevention, evolution in information technology, and reduced cost of services. Healthcare systems are becoming patient centric, and many are in the process of re-designing their systems to assure safe, efficient, timely, effective, and patient-centric care to meet needs. Ferraro *et al*. cited a UK Department of Health publication, "Diagnostic Services in 2020 and beyond: Visioning for the Future v1.9, December 2012" that puts the patient at the centre in terms of diagnostic services design, delivery, and evaluation.

Three main goals are proposed in the referenced document:

1. Improve the availability and access to information by the patient
2. Accelerate the adoption of new evidence-based diagnostic technologies
3. Re-design diagnostic pathways to facilitate access to well-integrated services

Greaves *et al* (Greaves *et al*, 2019) confirmed, suggesting that laboratory medicine will become more patient-centric based on the view that patients are increasingly becoming more proactive and better informed as they access information on the internet. Therefore, effective practice in laboratory medicine is required. Patient factors that have already started to disrupt laboratory medicine include chronic disease prevention, increased population, longevity, and patient demand for direct-to-consumer testing.

"The consumer is now at the centre of healthcare strategy of P4 medicine (predictive, preventative, personalised, and participatory medicine)."

The authors say that trends affecting how the laboratory services will operate include, (1) Integration of laboratory tests into care pathways; (2) empowerment of patients, and (3) digitalisation of care.

1) **The integration of laboratory tests into care pathways** will contribute to the continuum of care and help improve clinical and economic outcomes, whilst enhancing the multidisciplinary approach to patient care. The aim of a care pathway is to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimising the use of resources. A more efficient management of chronic diseases, centred on patients, is driving the switch to care pathways and the re-organisation of healthcare services, such as outlined in the Sláintecare programme, and is also stimulating more collaborative junctions between primary, secondary, and tertiary care sectors.

2) **Empowerment of patients:** In our aging population, the burden of chronic diseases is increasing globally and as the technologies of information and communication change, opportunities arise to empower patients in their own care. Several studies demonstrate that self-management processes relying on mobile health interventions are effective in improving self-management behaviour or patient reported outcome measures associated with chronic diseases. The authors postulate that empowerment, access to self-monitoring, the building of home care service and the global consumerisation trend will allow patients and the general population to be in control of ordering tests. These factors as well as direct-to-consumer testing will impact test ordering and potentially its regulation.
3) **Digitalisation of healthcare:** Neumaier, in a published paper in Clinical Chemistry and Laboratory Medicine in 2018 (Neumaier, 2018), suggested that disruptive technologies will fundamentally change the way laboratory tests are going to be ordered, carried out and interpreted in the future, and test results from various sources need to be curated to be of added value for the patient's condition. Wearables and implantable technology will quantify the concentrations for an unknown number of laboratory parameters, and the data will be stored in cloud services at the fingertips of the patient as the sovereign of his/her own data. A 24/7 online availability of health services will strengthen predictive medicine and may enable a vastly improved preventive system that is supported by deep-learning algorithms for clinical decision-making not only on behalf of the physician, but also the empowered patient (e.g., health bots). This will likely shift the current role of laboratory medicine as a central provider of diagnostic information from a "hidden champion" towards a higher visibility redefining the patient-physician-laboratory relationship. For example, accessing digital health data will allow laboratory medicine to contribute to the medical dialogue more efficiently than is often the case today. From this perspective, this will require major readjustments in the way we execute our profession, and it will also need new concepts of education and continuous professional development.

Other authors like Greaves *et al* (Greaves *et al*, 2019), talk about the new generations of electronic medical record systems that digitally connect information from one practice, provider, or facility to another. Interoperability between systems will be crucial for efficiency and effectiveness. They also suggest that artificial intelligence could also influence the process of ordering or activation of reflex or repeat testing. Intelligent ordering systems coupled to data analysis and machine learning could also mean more efficient tools for appropriate test prescription is another possibility. They suggest that digital and dynamic pathways involving multidisciplinary teams and more efficient integration of primary and secondary care sectors will facilitate the delivery of value-based-healthcare systems. This will have an impact on better control of test ordering and will have a significant economic impact.

Technologies

LIMS

A national laboratory information system should create and support an integrated national pathology record supporting diagnostic laboratory medicine, healthcare quality efficiencies and improve patient outcome. It should incorporate all major laboratory disciplines and be underpinned by electronic ordering and reporting. A key element of a national LIMS should include contingency and disaster recovery. Furthermore, a national LIMS should support and drive laboratory modernisation and consolidation of services where appropriate.

From an end-user perspective (e.g., clinician), the system will allow paperless e-ordering and the electronic provision of results. This will not only improve ease of delivering care but increase opportunities to conduct clinical audits, implement decision support capabilities, streamline results to clinical care pathways, and receive/provide remote advice on results.

To ensure the success of the system, key areas that must be addressed include interoperability and connectivity with other clinical systems and Electronic Health Records based on standards including HL7 and standardised coding (e.g., LOINC, nationally agreed catalogues and datasets). Furthermore, this could be supported by the provision of a single patient identifier underpinning a single patient record.

Full details of the NGS Matrix can be seen in Appendix 4.

Key Considerations

- The priority based on feedback from laboratories is universal access to electronic ordering, reporting, and transfer of results.

Next Generation Sequencing

Next generation sequencing (NGS) is a technology that determines the order of nucleotides (sequence) in entire genomes or targeted regions of DNA or RNA. The motive for doing so is to study variations that may or may not be associated with clinical diseases or other biological phenomena relevant to the patient. This is particularly relevant in the field of oncology where NGS can be employed in personalized medicine, whereby the profiling of a patient's disease can facilitate targeted therapies. Beyond oncology, NGS will also be a vital innovation in all pathology disciplines. Outside of pathology laboratories it is already a mainstream technology used in genetics and genomics, which is being considered in the national genetics and genomics review.

Whilst this technology is set to revolutionise the way in which care is delivered, significant investment is required to stand up such an offering. Firstly, financial investment will be required to obtain both the relevant sequencing equipment but also to address the crucial associated ICT considerations. NGS generates large multi-gigabyte raw datasets requiring integrated and operational systems that allow the collection, analysis, and storage of results. In addition to the equipment and processing systems, the most important investment made by the HSE will be in the appropriate training of its staff, particularly in the analytical and interpretive skills required for NGS, molecular diagnostics, and bioinformatics. Additional consideration will need to be given to regulation and registration.

The implementation of NGS is already underway in laboratories in Ireland, however, it is occurring in an ad hoc nature and without a strategic plan. It is believed that a more centralised approach would be sensible during the initial roll out owing to the rapidly developing nature of the technology and the critical mass of knowledge and expertise required to process the data. As the technologies then become more automated, a more distributed roll-out would be merited. It must also be appreciated that the strategies for implementation, particularly concerning training requirements, will differ depending on the exact use-cases.

Full details of the NGS Matrix can be seen in Appendix 5.

Key Considerations

- Next generation sequencing NGS requires a significant computation capacity. A policy and framework for the provision of this capacity must be defined.
- Bioinformatics training is required to ensure that appropriately qualified staff are available to analyse primary data from NGS analyses.
- Training and qualification needs for the interpretation of data from NGS analyses must be provided for each clinical discipline.
- Integrate more closely with clinical services to aid variant interpretation.

"The National Office for Genetics and Genomics will provide oversight and governance of genetic and genomic service delivery in Ireland, driving the implementation of the National Genetics and Genomics Strategy to address urgent service deficiencies, and lead on longer term continuous service development.

As part of the Strategy implementation, the National Office for Genetics and Genomics will build upon the work of the 'National Working Group to Inform the Strategic Direction of Laboratory Medicine' and conduct a comprehensive capacity and demand analysis to establish the current baseline in terms of specific genetic and genomic capability, capacity and technology use to enable the modernisation and harmonisation of laboratory services, workforce development and recognition across the country.

The National Office for Genetics and Genomics will continue to engage with the 'National Working Group to Inform the Strategic Direction of Laboratory Medicine', to ensure alignment in the strategy implementation."

Digital Pathology

Digital pathology (DP) involves the acquisition, management, sharing, and interpretation of pathology information (including slides and data) in a digital environment. Digital slides are created when a scanning device is used to capture high resolution images of blood or tissue specimens on glass slides which can then be viewed on a computer screen or remotely. Benefits include, but are not limited to, remote reporting (including expert reviews), reduced TAT, enhanced storage and archiving of images for the purposes of review, as well as greater opportunities for training. Furthermore, the provision of digital images of histopathological samples opens the specialty to the prospect of machine learning and artificial intelligence (ML/AI). More than 60 ML/AI applications relating to DP have been approved by the US FDA to date, while Northern Ireland are in the process of moving their histopathology services entirely to DP in recent years.

Despite the stated benefits, there are currently no laboratories in Ireland accredited for DP albeit some sites have invested in scanners for smaller scale DP use. Moving forward, investment is required into the hardware, power and IT specifications needed to stand up a DP service. The benefits to clinician and scientist training must also not be understated. Similar to NGS, due consideration must be given to the supporting ICT infrastructure including connectivity to laboratory information systems and the ability to store images in the cloud (similar to the Irish National Integrated Medical Imaging System – NIMIS).

Full details of the DP Matrix can be seen in Appendix 6.

Key Considerations

- As with NGS, digital pathology (DP) requires significant computational resources and therefore a policy and framework for implementation must be developed.
- For DP to be successful it requires a shared database that is accessible for all connected networks. Discussion with the relevant professional body for pathologists should be initiated with a view to piloting a national system.
- The future provision of expertise and cover for specialist services should be considered.
- Artificial intelligence assisted image analysis is a likelihood in the future and any bioinformatic training scheme should reflect this.
- A national approach to procurement of DP infrastructure.

Bioinformatics

Bioinformatics is an interdisciplinary field that focuses on the storage, retrieval, and subsequent analyses of large volumes of biological information. It marries computer science with biological analysis, and examples of data analysed includes DNA, RNA, amino acid sequences, or annotations about those sequences. Scientists and clinicians use databases that organise and index such information to help improve our understanding of health, disease, and best practice. It now becoming a critical enabling technology for modern medicine as the volume of data produced annually continues to grow through drivers such as NGS for genetics, oncology, and pharmacogenomics.

Whilst crucial to the future of the Irish health service, there are currently no funded clinical bioinformatic training schemes in Ireland. Other countries around the world have recognised the importance of this and note should be taken. In the UK, a training scheme with dedicated funding is available for scientists working in bioinformatics.

Full details of the Bioinformatics Matrix can be seen in Appendix 7.

Key Considerations

- As an extension of both computer science and biology, bioinformatics is a major requirement for NGS and DP and an area of expertise that is deficient within the Irish healthcare system.
- A national plan for the recruitment and training of scientists working in clinical bioinformatics is required to ensure that the necessary expertise can be put in place to support these technologies.

Cell Therapy

Cell therapy is a promising, rapidly advancing field with the potential to transform medicine across disease areas where significant needs exist. It involves the placement of new, healthy cells into the body to replace those that are diseased or damaged, or to modulate the function of existing cells. Furthermore, with the utilization of immune cells, cell therapy can be used to remove dysfunctional and disease-causing cells. For the patient, this regenerative technology could mean halting/reversing disease, restoring damaged organs, and ultimately curing many life-threatening conditions. CAR-T cell therapy is an example of such a treatment.

Like any other medicine, cellular therapies are heavily regulated from a manufacturing and pharmacovigilance perspective, with an emphasis on quality, safety, and efficacy. They are currently undergoing clinical trials around the world, including in Ireland. They require new ways of working cross-functionally in healthcare organisations, new skills, and competencies, in addition to oversight by regulatory authorities (e.g., HPRA and EMA). A key next step in rolling out this future of medicine is establishing a national procurement organisation would allow faster implementation and rollout of both new clinical trials and new advanced therapy medicinal products.

Full details of the Cell Therapy Matrix can be seen in Appendix 8.

Key Considerations

- Supporting structures are to be evaluated and developed, which will support and facilitate the development of new clinical trials and adoption of proven technologies.
- Where technologies currently exist in cell therapy, efforts should be made to repatriate services currently being delivered by other countries.
- Innovation and exploration should be sought into new area of cell therapy that will transform the way that care is delivered.
- It is imperative that as cell therapies, a robust regulatory environment must be defined and delivered to ensure the quality, safety, and efficacy of technologies used.

Pharmacogenomics

Pharmacogenomics is the study of how one's genome impacts their response to certain drugs. The field combines pharmacology and genomics to develop safe and effective treatment plans based on one's genetic makeup. This would supersede the current approach to pharmacology which is a "one size fits all" approach, where responses and reactions vary unpredictably between patients. It is believed that 30% of variability in drug response is attributable to genetic variation. This is an area with enormous growth potential and organisations around the world, including the World Health Organisation (WHO) and National Institute for Clinical Excellence (NICE), have called for a personalised approach to care.

Genetic variations impacting pharmacokinetics in individuals are common and therefore a robust screening system for such variations is essential, to allow clinicians to prescribe therapies in a manner more tailored to the patient, whilst minimising the risk of interaction and toxicity. Without appropriate investment into the equipment, specialist staff training, and infrastructure, the HSE may need to rely on the provision of private providers or services in other jurisdictions, coming at considerable expense. Certain technologies relating to pharmacogenomics (such as whole genome sequencing), will require specialist diagnostic centres. However, many pharmacogenomic tests are less technically demanding and may be best delivered in existing hospital laboratories. For example, other jurisdictions have incorporated genotyping services into existing laboratory disciplines such as clinical biochemistry.

The training, infrastructure, and staffing needs must apply to primary, secondary, and tertiary settings taking account that the majority of prescribing occurs in the community. Larger hospitals in Ireland will likely need facilities to perform the more routine genotyping services, while specialist centres will perform more specialist work. In terms of staffing, it is envisaged that a mixture of scientific disciplines will be required to perform and undertake the interpretive work required and will consequently require appropriate training. Finally, it is vital that a robust infrastructure is in place to manage the storage and accessibility of pharmacogenomic data within the HSE, considering the different settings in which it may be required. It may be wise to have a central repository with due care and consideration being given to the ethical, legal, and GDPR aspects of such a service provision.

Full details of the Pharmacogenomics Matrix can be seen in Appendix 9.

Key Considerations

- Consideration should be given to the formation of a working group on pharmacogenomics to include clinicians, scientists, and pharmacists at a minimum, drawing those with experience where possible.
- Identify pharmacogenomic markers with defined clinical benefit and determine if testing is likely to require implementation in either acute or chronic care.
- Prepare rollout strategies for testing of acute and chronic care pharmacogenomic markers.

cfDNA

Cell-free DNA refers to all non-encapsulated DNA present within the blood stream, as a result of apoptosis or cell necrosis. Typically, such fragments would be removed from the circulation by macrophages (a subtype of white blood cells). However, in certain situations (such as the overproduction of cells in malignancy), more fragments of cfDNA are created resulting in detectable levels within the blood stream. Resultantly, such fragments of DNA can be analysed as part of NGS to determine their cell type of origin.

Within the field of oncology, this poses a fantastic opportunity to replace current means of tissue diagnosis. Presently, and with few exceptions, invasive biopsies are required to ensure sufficient tissue is present to confirm/refute a diagnosis. The adoption of such technology would likely present an expansion of existing laboratory services, reduce theatre time to obtain biopsies, and hopefully improve patient outcomes through faster and easier diagnosis. It must be noted that whilst the efficiencies realized would mainly be in the clinical domain, and expansion of laboratory services would be required in line with NGS.

Whilst cfDNA has specific applications within the field of oncology and transplant medicine, it is already common practice within fetal medicine. Four examples of applications are:

- Identification of fetal anomaly.
- Screening for trisomy.
- Determination of fetal rhesus D status.
- Non-invasive prenatal diagnosis (NIPD).

Within the realm of fetal medicine, there are two primary methods of introducing this technology. The first is via NGS which places significant reliance on bioinformatics as well as major extraction, amplification, and detection systems as described above. Alternatively, within fetal medicine, there is the opportunity to implement closed systems, which could be used for the identification of Trisomy but requires minimal bioinformatics capacity. Closed systems are small in nature and would be easily accommodated within a standard laboratory setting with appropriate governance.

The introduction of cfDNA technology would be an essential step in reducing reliance on UK laboratories. At present samples are packaged and tracked to British laboratories owing to a lack of capacity 'on-island'. This would also improve the availability of reports with direct connectivity to Irish LIMS systems.

Full details of the cfDNA for Oncology and Fetal Medicine Matrix can be seen in Appendix 10 and 11.

Key Considerations

- Much of the infrastructure required for the implementation of cfDNA testing is common to next generation sequencing (NGS) so an established roadmap for NGS rollout is required to effectively plan for implementation of this technology.

Estimates of Implementation Complexity

As part of the appraisal process, the above technologies were compared against five key areas for ease of implementation. The assessment of the technologies and scientific practices are shown in *Table 1*, whilst the criteria and associated scales for the assessment are shown in *Table 2*.

	NGS	DP	BI	CT	PG	cfDNA – O	cfDNA – FM	LIMS
Training	5	3	8	5	5	7	6	5
Engagement	5	5	8	6	5	5	4	8
Education	3	5	3	10	7	7	7	8
Clinical Support Structures	5	5	5	1	5	7	8	10
Technical Support Structure	9	5	9	5	9	7	5	5

Table 1: Complexity of implementing advances in technology and scientific practices

NGS: Next Generation Sequencing
DP: Digital Pathology
BI: Bioinformatics
CT: Cell Therapies
PG: Pharmacogenomics
cfDNA-O: Cell-free DNA Oncology
cfDNA-FM: Cell-free DNA Fetal Medicine
LIMS: Laboratory Information System

Training	1 – Staff are already trained.
	5 – Schemes are in place but not widely adopted.
	10 – No training schemes are in place and would be difficult to implement.
Engagement	1 – Very few perceived barriers to uptake.
	5 – Moderate barriers which can be overcome with training and education.
	10 – Significant education and training required to enable.
Education	1 – Recognised qualification available.
	5 – Qualifications available but not accredited.
	10 – No formal education available on this topic.
Clinical Support Structure	1 – Will use existing infrastructure.
	5 – Can use existing infrastructure if modifications are made.
	10 – Existing infrastructure insufficient and requires development.
Technical support services	1 – Will use existing infrastructure.
	5 – Can use existing infrastructure if modifications are made.
	10 – Existing infrastructure insufficient and requires development.

Table 2: Matrix for scoring complexity of implementation

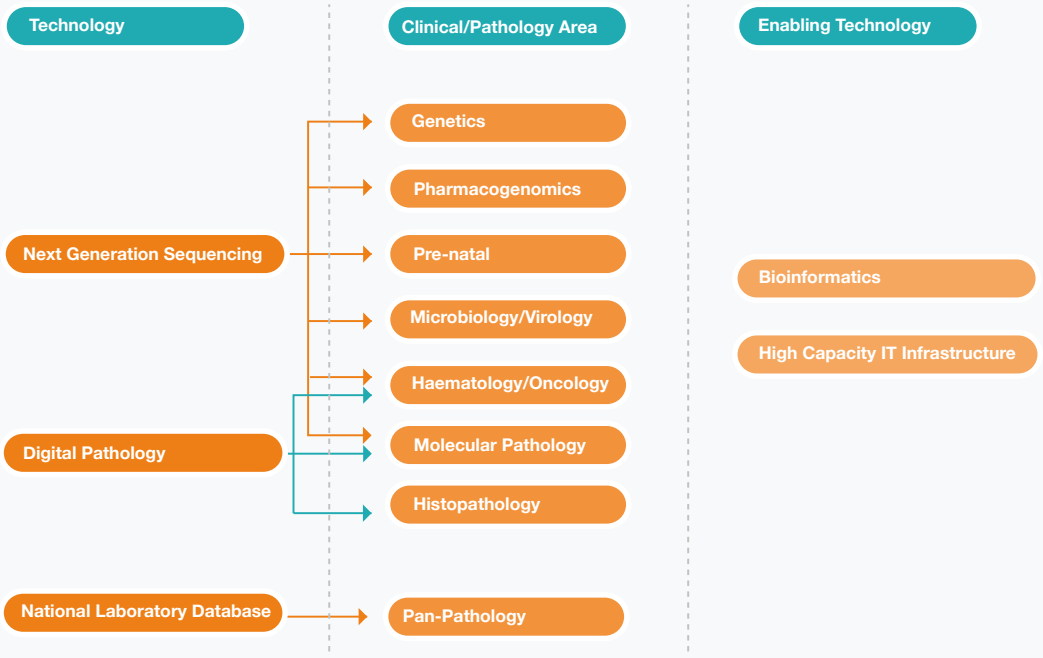
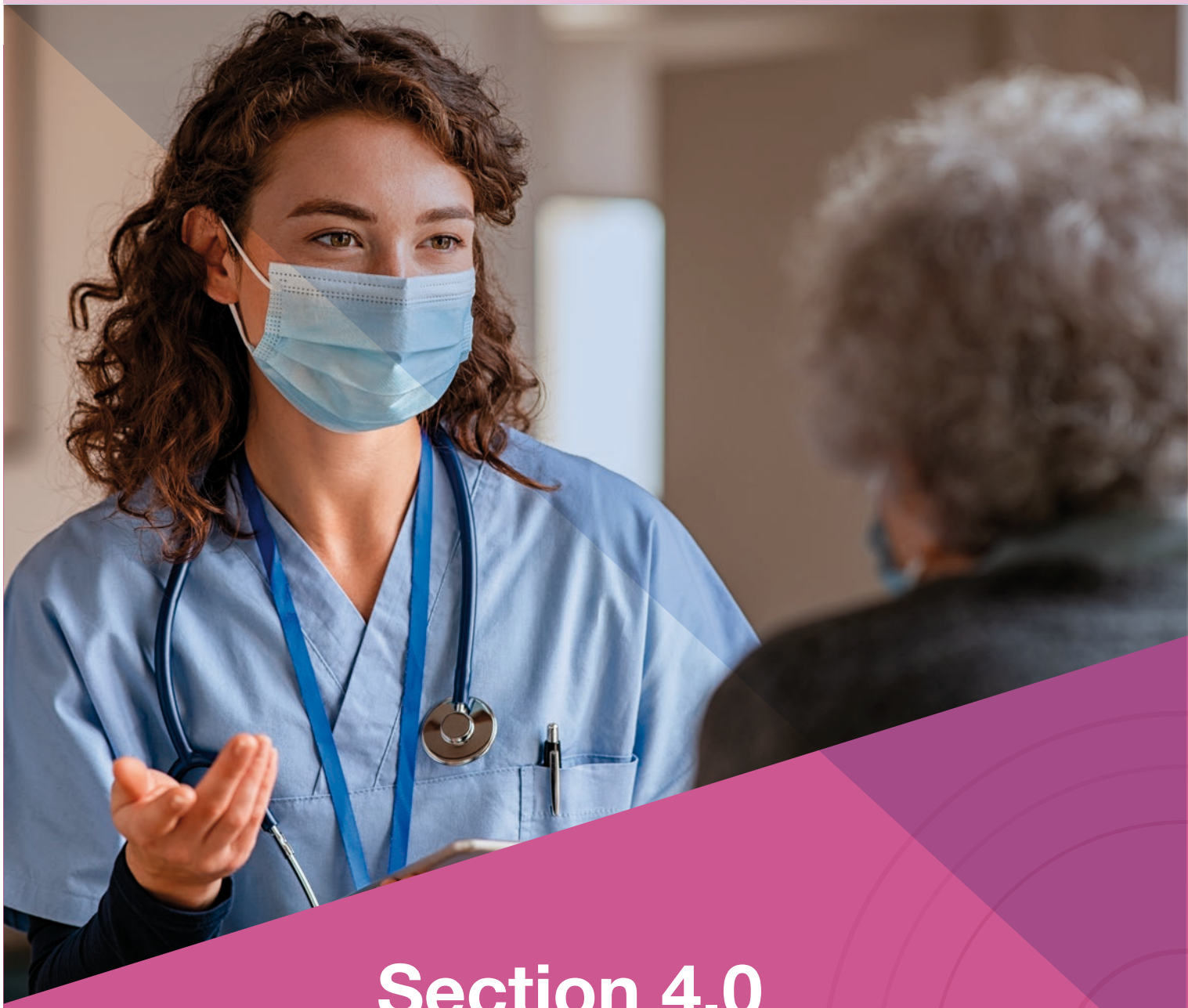


Figure 21: Interaction plot between technologies and pathology

Summary

Technological and scientific practices are rapidly developing and have the potential to revolutionise the way in which laboratory medicine is delivered. However, in order to keep pace with such advancements, it is vital that appropriate supporting structures and investments are implemented to ensure their success. This will ensure patients' needs are supported as part of a high-quality service and that patient safety is kept at the heart of all decision making. To note, whilst the above summaries serve to identify those technologies with revolutionary potential, further research and planning is required to ensure their safe incorporation into practice.



Section 4.0

Consider relevant international models of care and lessons learned to inform future direction regarding models of care and funding (consider 3-4 international models of best practice that would have similarities to the Irish healthcare system).

Funding for Pathology and Laboratory Medicine

Overview of Healthcare System Funding

As described by Lameire *et al* (Lameire, 1999), there are three primary models of healthcare funding as shown in *Figure 22*. Ireland would be most akin to the Beveridge model, with most healthcare expenditure being financed through general taxation and a universal social charge (USC) levied on employees and the self-employed. In the Central Statistics Office press release for Health Accounts 2019 (CSO, 2019), government financing accounted for 74% of total health expenditure with the remainder being attributed to 'out of pocket' (14%) and health insurance (12%) spending.

Current funding of acute hospitals is complex with multiple varied sources of income being received. Firstly, the Hospital Groups receive annual budget allocations from the HSE. This is for both inpatient and day-case related activity and is centred around Diagnostic Related Groups (DRGs). At a high level, patients are classified into a limited number of DRGs which are supposed to be clinically meaningful and broadly homogeneous in their consumption of resources. Each DRG has a specific weighting applied which has been calculated based on average treatment costs of patients falling within these DRG. As of 2022, 75% of funding was through a general DRG budget with the other 25% being block grants. Block grant funding is currently used for services outside of day-cases and in-patient care such as the Outpatient Department, Emergency Department, diagnostics, and mental health. By comparison, in the UK all hospital services are paid on the basis of Healthcare Resource Groups, which are similar to DRGs.

In addition to HSE budget allocations, acute hospitals may also receive funding from the following activities:

- Private health insurance.
- Provision of clinical services to external entities including laboratory services.
- National Cancer Control Programme.
- Patient 'out-of-pocket' expenses.
- Grant funding.
- Car parking charges.

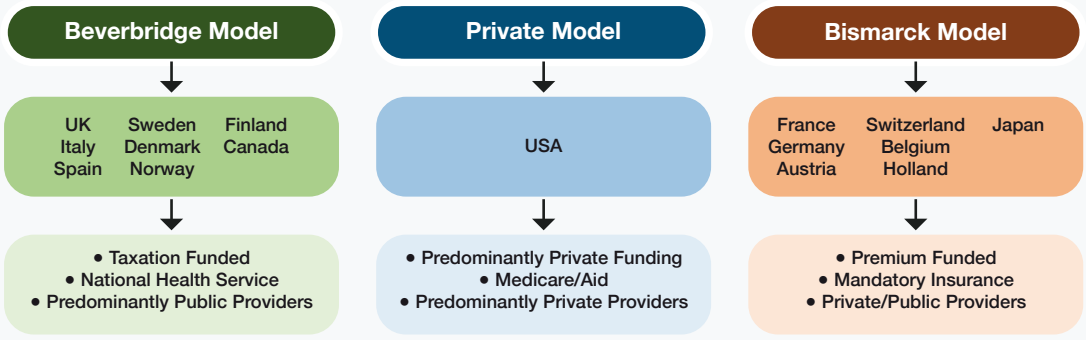


Figure 22: Models of healthcare funding

Funding for Diagnostic Laboratories in Acute Hospitals

Diagnostic laboratories in the public health system in Ireland are primarily funded directly from their respective hospital's budget. Their allocation is typically reviewed on an annual basis to analyse any expected cost growth for the subsequent year in addition to any new agreed services or replacements of critical infrastructure. The latter is generally highlighted in annual pre-budget submissions to the hospital's finance department for consideration for inclusion in their respective 'Estimates' submission. Hospitals, via their Hospital Groups, submit "Unmet Needs" as part of their 'Estimates' submission which incorporates key infrastructure requirements to meet current and future services' needs. This is completed on an annual basis by all departments within a hospital and may not translate into a tangible outcome.

In addition to funding provided directly by the hospital, some laboratories receive specific ring-fenced funding from health agencies for the provision of selected services. Examples include, but are not limited to, the National Cancer Control Programme (NCCP) and the National Screening Service (NSS) for testing including cancer molecular diagnostics and breast screening pathology.

As the DRG payment system is now the policy for funding the acute hospital system, it is essential that diagnostic laboratories understand their cost base and develop a weighted test costing system for their services. Laboratory costing methodology must be developed to so that all tests (on a weighted basis) have a marginal cost and fully absorbed cost calculated to allow subsequent contribution to patient level costings and inadvertently the associated DRG cost. Such costings with the provision of a profit may then also be used in the provision of SLAs to external entities. Of note, this makes reference to only one of many functions of diagnostic laboratories – the receipt, processing, accurate analyses of specimens, and issuing of interpretive reports.

Acute hospital laboratories are responsible for the processing of a significant portion of specimens from the Irish general practice network. The impact of such requirements varies across the country with the percentage of testing in acute hospital labs ranging from 33% to 66%. The percentage in paediatric and maternity hospitals would be much lower. Moreover, the number of referred samples is increasing significantly with an approximate nationwide increase of 5% annually. Referred samples are the transfer of samples from a laboratory/hospital to an external laboratory for testing, examination, and reporting. At present, no direct funding mechanism exists to support this sizeable workload in terms of pay and non-pay revenue resources. Instead, funding is incorporated into the hospital's overall allocation. An exception to this, is the recent agreement to support the provision of NTProBNP/BNP for GPs as part of the integrated care programme for the management of chronic disease in primary care.

In most countries operating under a variation of the Beveridge model of funding, the state funds pathology and laboratory medicine services including those specimens referred in from general practice. However, the exact reimbursement mechanisms from the users (hospitals/clinical departments) varies. Privatised or Bismarck systems by contrast typically operate a fee per service contract with options for volume discounts.

Cost of Pathology in Ireland

Figures from the Healthcare Pricing Office (HPO, 2019) state that acute hospital services had an expenditure level of €6.025 billion in 2019, with pathology costs of €0.452 billion (excluding blood product transfusions). This equates to a national average expenditure of 8% within the acute system. Little variation was seen between medium to large acute sites across the nation. It is important to note that GP-referred tests and external hospital referred tests (between laboratories) are included in the costs. The income derived however from these referrals are not included in the figures and would go towards defraying some of these non-pay costs from larger laboratories providing such services. The total annual healthcare budget in 2019 was €17.238 billion meaning pathology expenditure was at 2.46% of total spend.

When compared with similarly developed countries, the Irish spend on pathology is similar. In 2017, Australia reported that pathology equated to 2.7% of overall costs whilst Germany reports that approximately 2.5% of costs reimbursed by German statutory health insurers are laboratory related expenses. However, one must appreciate the differences in overall health systems. In England, the total acute hospital expenditure was £56.8bn in 2019 with pathology costs of £2.2bn (RCPath, 2022). This is the equivalent of 4%, however, it is not clear whether GP referrals costs are included in this calculation. This figure is less than the quoted £2.5bn spend in 2006, as stated in the Carter Report (Carter, 2008).

Key Funding Requirements

The following represent key specific infrastructure and resources that must be addressed when considering funding for pathology and laboratory medicine services in the future:

ICT Infrastructure for Communications and Digital Transformation

a) *An appropriate and modern laboratory information management system (LIMS)*

A robust LIMS is vital and central to the operational management of laboratory workflows in addition to facilitating the meaningful use of data generated in a laboratory. Moreover, it allows electronic communication of patient laboratory test requests to/from end users in a variety of settings and facilitates demand management and optimisation initiatives. Laboratories cannot function effectively or efficiently without such systems and this requirement is becoming even more so as laboratory medicine evolves at pace with the introduction of more complex testing such as genomics. The introduction of an appropriate LIMS is seen as both critical and urgent.

b) *Interoperability between LIMS and other internal systems*

In order to ensure the successful implementation of a LIMS system, interoperability with other internal systems within a laboratory is vital in addition to external systems including EHR's, financial systems, registries, GP practice management systems, and other clinical systems within the hospital (e.g., CVIS – Cardiovascular Information System). Such interoperability is seen as essential for the successful novel technologies including digital pathology which would require any LIMS system to be linked with histology automation platforms. It is essential that all information acquired from analytical instruments and/or other systems resides in a central informatics hub.

For example, Central Norway introduced an agreed LIMS followed by automation across all its hospital laboratories in a fully networked system to optimise connectivity and standardisation. It is interesting that having chosen EPIC system for their LIMS, the hospitals followed by accepting EPIC as their EHR system for better connectivity. This approach is worth considering in the Irish context too, due to the complexity requirements for an integrated LIMS solution and the reported fact that about 95% of clinical pathways rely on patients having access to efficient, timely and cost-effective pathology services.

c) *Order Communication*

Order communication involves the receipt of electronic test requests with an accompanying barcode labelled specimens that is readable on a LIMS system. The barcode is specific to both the patient in question and the required tests, allowing the linkage of results to the patient's health record as soon as results are authorised. This goes beyond EPRs and includes linkage with other clinical systems such as GP practice management systems. Order communications are also of importance for inter-laboratory transfers of specimens. This can be achieved through having the same version of LIMS or using interfaces for disparate systems.

d) *Near-Patient Testing Management System*

With the increasing use of NPT, it is essential that such a middleware system is made available to allow interconnectivity between the in-vitro medical devices and the EHR in addition to other clinical systems including the LIMS.

e) *Digital Pathology*

Digital pathology encompasses the acquisition, management, sharing, and interpretation of pathology information in a digital environment. Digital slides are created through the capturing of glass slides with a scanning device, to provide a high-resolution digital image viewable on a computer/mobile device. This technology is an essential enabler to allow for the option of off-site reporting and the introduction of emerging technologies including artificial intelligence. The specifics of this are discussed in *Section 3*.

Automated Analytical Systems

Core automated analytical systems must be considered for investment to support the large workload volumes in haematology, biochemistry, serology, and immunology laboratories. Of note, they can be tailored to suit all laboratory workloads using a modular system approach. Such automation should incorporate pre-analytical sample handling, sample tracking, and post-analytical sample archiving and retrieval systems where appropriate – particularly for larger laboratories. Core automated analytical systems in microbiology and histopathology must be made available and proportionate to the workload volume and complexity that will enhance the quality (more effective and efficient systems) and safety of services in support of the optimisation of patient care. Laboratories providing genetic/genomic services will require the appropriate automation, bioinformatics, and specialised personnel to fulfil their remit in line with international best practice. In addition, there must be appropriate infrastructure and other supporting technologies to support these services as discussed above and in *Section 3*.

Laboratory Accommodation

In order to accommodate the expanded remit and developing functions of the laboratory, appropriate working environments must be provided. This includes the provision of appropriate space with the incorporation of fallow capacity to incorporate new technologies and new service developments. Where necessary older and unsuitable facilities should be replaced by new infrastructure and in doing so consideration must be given to its strategic location with the hospital. Factors that must be considered are proximity to acute clinical services, specialties, theatres, and clinical research bodies to enhance and support clinical care, collaboration, research, and innovation. A critical piece of hospital infrastructure is a pneumatic tube transport system for transport of blood samples to the laboratory, which will optimise the turnaround times for issuing reports to clinical departments. Other future innovations should also be considered, such as the adoption of robotics for specimen handling/processing, which can again free up a constrained workforce.

Workforce

a) Recruitment and retention policies

Investment is required to stand up recruitment and retention programmes to attract and retain key individuals and staff groups. These are discussed in greater detail in Section 2, however, at a high level include:

- CPD/CME budgeted programmes
- Increased opportunities for flexible working arrangements with shorter working weeks
- Hybrid working opportunities where appropriate
- Opportunities for staff development and promotion
- Staff education and learning programmes

b) Review of staff structure and profiles

The need for this is to ensure the efficient use of human resources to best meet service needs, keeping at heart the needs of the patient and the population more generally. Specific areas to be looked at include the upskilling of individuals as required for the adoption of new technologies as well as the opportunity to expand the workforce as required to meet clinical needs. An example would be to recruitment of more bioinformaticians to support the development of genomic medicine.

Furthermore, the method of service provision should be reviewed with the aim of improving systems that enhance patient care in terms of quality and safety whilst also being mindful of employee's health, wellbeing, and professional development.

Specific Funding Challenges to be Addressed

Currently, there are no specific budgets for the following activities and require attention moving forwards:

1. **Planned replacement of analytical equipment through capital purchase**

   At present, most high-volume automated systems are acquired through rental/purchase, leases, or managed service contracts.

2. **Implementation of NPT across key acute areas as required**

   Costs will include the acquisition and training of personnel, consumables, implementation of quality assurance in addition to the acquisition of an appropriate ICT infrastructure required to stand up the service.

3. **Digital transformation of workflows**

   This includes the automation and ICT infrastructure required to optimise pre-analytical, analytical, and post-analytical stages of the laboratory's processes. Planned investments should be aligned to the HSE's overall ICT strategic plans and be highlighted as part of the "Unmet Needs" of the service.

4. **Supporting the development of new clinical services**

   A significant challenge is the identification of funding resources as part of business case development. Clearer streams of funding for new service developments should be made available, particularly for the acquisition of the required personnel.

5

General practitioner test referrals

Owing to significant variations across the nation and the exponential rise in referrals, consideration should be given to funding GP test referrals separately. This would include the supplies required in addition to the cost of delivering the service.

6

Supporting mandatory CPD programmes for professional staff

Currently such programmes are self-funded impacting the development of key individuals in addition to adversely affecting staff members financially. Going forward, funding for mandatory training associated with professional State registration should be considered as a separate budget. It should be noted however, that some larger hospitals do have funding to provide partial support for post graduate courses and other short courses on a limited basis.

7

Achieving and maintaining accreditation/regulatory compliance

This includes the additional resources to support accreditation and regulatory compliance. Further details pertaining to this matter are in *Section 2*.

8

Research and development projects

This includes the implementation of new services that improve the quality and safety of services for patients, whilst also potentially offering cost reduction opportunities at the clinical interface. An example is the introduction of primary care NTProBNP to detect heart failure and prevent unnecessary referrals.

Currently, funding is based on historical costs, including a hospital's annual financial allocation, some of which comes through the DRG system and the rest from block grants for services. Whilst operational, this is not optimal with nil ring fencing of budget for diagnostic laboratory services. The only exceptions to this involve the provision of specific funding of new services such as NCCP funding for specific histopathology and molecular diagnostic services. Reference services also do not have any ring-fenced funding, and this comes through the aforementioned block grant system.

When considering how diagnostic laboratories should be funded in the future, it is important to first understand their overall role in patient care pathways. Their remit extends greatly beyond the analysis and timely reporting of results and examples of other responsibilities include:

- Participation in MDTs for services such as oncology and rare diseases.
- Participation in transfusion and hemovigilance committees.
- Participation in the Antibiotic Stewardship Committee.
- Microbiologists leading Hospital Infection Control teams and the development of related policies.
- Involvement in local, regional, and national committees.
- Clinical and laboratory consultations support patient care and management in the community and in hospital.

Funding sources must address and appreciate the contributions of laboratory diagnostics to value-based-care in both their respective institution in addition to the community it serves. Other considerations include (a) GP workload requirements as previously described (b) additional services such as the phlebotomy services operated by major Dublin hospital laboratories. This is of particular importance as the DRG system expands with only the cost per test/service being reflected in the DRG price and not the other major roles the laboratory plays as above.

Managed Service Contracts

A popular methodology employed internationally to optimise the financial management of diagnostic laboratories is through managed service contracts (MSCs). MSCs are flexible and bespoke contracts with a service provider that are based on contractual KPIs, that facilitate access to new technology, innovation, supply chain management, continuous improvement expertise and related services. They support the establishment of the laboratory network model and have the potential to deliver significant efficiency savings without the requirement for capital expenditure to purchase and replace high value-assets. They can encompass all equipment, consumables, maintenance, and supporting services to provide a complete end-to-end solution.

The laboratory would receive a choice of approved equipment providers allowing the selection of high-quality solutions whilst also allowing the creation of strong relationships with manufacturers. Moreover, it allows the provision of a broad scope of services, under a single contract, with the buying power to negotiate costs savings, whilst remaining flexible to assess services/suppliers during the contract. This approach is widely deployed in the UK and is becoming more widespread in Ireland too. This will help ensure the standardisation of equipment and methodologies across a laboratory network whilst also helping in achieving best economic value. Of note, MSCs rely on expert procurement input to define specifications as well as the monitoring of KPIs to ensure the provider delivers on the agreement. This is one example, but alternative options should be examined for the procurement of technologies and expanding infrastructure.

National Speciality Funded Services

Within the HSE, there are a number of funded national specialty services across the system. Their development has been on an ad hoc basis, and their funding and development must be considered in any future strategic development work.

Whilst funding is provided for such services on an individual basis, funding is often not appropriately ring-fenced and is received into the acute hospital system via a block grant. The devolution and management of funding in line with allocated budget should be reviewed. Technology in diagnostics is rapidly changing and advancing, and there is a constant challenge to maintain and replace equipment. From a funding perspective, the allocation must keep in line with costs in relation to these advancements.

There are a number of laboratories providing specific national services on the basis of their clinical and/or scientific experience and accreditation status. These services are funded by Service Level Agreements (SLA) where an agreed price is paid for such services from the referral laboratory. Inter-agency billing has been an issue for many years and perhaps another approach should be reviewed, such as, direct charging to the HSE for referred tests from other laboratories in the public system based on an agreed tariff.

Modernising of Pathology and Laboratory Medicine Services

Current Management Structure

Pathology and laboratory medicine services in the acute hospital sector is part of the hospital's internal departmental structure. For the larger Model 4 hospitals who have adopted the clinical directorate model, the laboratory management structure comprises a laboratory clinical director and a laboratory manager with some having a business manager and/or a quality manager as part of the leadership team. The laboratory clinical director and laboratory manager represents the directorate at executive meetings and report directly to the CEO and the COO as appropriate, with a strong liaison with other departments, such as, Head of Finance, HR, and Quality and Patient Safety and other clinical and service directorates.

The introduction of the clinical directorate model in 2009 incorporating "executive authority" for the laboratory clinical director was described as one of the most significant changes to occur in the Irish healthcare service for many years. This new model was heralded to represent an unprecedented opportunity for change through clinical leadership. The purpose of the clinical directorate model was to achieve the best clinical outcomes and experience for patients within the available resources through the involvement of clinicians in leadership positions, working closely with other key staff including management, nursing and health and social care professionals in a collaborative manner. It was introduced however without any reform of the existing system of management, without a project plan to outline this significant proposed change and without a mandate to the acute hospital system for implementation (HSE, 2017).

Many of the Model 4 hospitals have adopted this model in Ireland. In terms of the pathology and laboratory medicine directorate, the laboratory clinical director, and laboratory manager are the key people responsible for setting strategic direction in consultation with heads of department and other key stakeholders and must be aligned to the hospital and HSE strategies and objectives. There are variations to the pathology and laboratory medicine management structure across hospitals with a business manager or quality manager as part of the management team in some directorates. The pathology and laboratory management team of laboratory clinical director and laboratory manager report into the hospital CEO and the COO as appropriate. They have monthly management review meetings with the executive team comprising the CEO, COO, Director of Quality and Patient Safety, HR Director, Finance Director, Director of Nursing, Medical Director, and other directors as appropriate. At these meetings, the directorate team gives a report on the directorate's performance against a number of agreed key performance indicators (KPIs) covering all the areas of service provision, such as, meeting agreed clinical/business needs of the specific clinical services in the hospital, finance and budgeting, workforce issues, education and training, quality, patient safety and accreditation, risk register review, capital investment requirements, and other operational needs etc.

This model appears to work well in Model 4 hospitals and provides the opportunity for all directorate management teams to meet and share their experience and also discuss their needs from other directorates. However, no study has been published to assess the impact overall within the HSE hospitals using them. Presently, we have Hospital Groups and working towards developing new Health Regions that will have a number of Model 2 and 3 Hospitals together with Model 4 hospitals as well as community service areas and so the directorate structure may have to be flexibly adopted across all hospitals in the Health Region, if that structure is maintained.

In 2011, The National Clinical Care Programme for Pathology was established as a joint initiative of the HSE Clinical Design and Innovation and the RCPI Faculty of Pathology in 2011. The programme aims to support all hospital clinical laboratories to achieve the highest standards of quality and efficiency. Its objectives from the beginning included the following:

- Supporting the implementation of a national pathology network and modernisation programme based on a whole-system approach with co-operative hubs and spokes organised according to clinical need.
- Co-ordinating the pathology modernisation activities of individual laboratories using the Ten Principles for Laboratory Modernisation framework, integrated with reform in the organisation and delivery of health services.
- Modify referral patterns for specialist tests by developing a national network of specialised laboratory services, ensuring that in-sourcing and out-sourcing of tests is appropriate.
- Developing a National Pathology Catalogue; laboratory handbook of national guidelines and order sets for common clinical diagnostic problems which lead to large scale laboratory investigations, so as to assist in demand management.
- Determining and monitoring laboratory quality, costs, and user satisfaction in Ireland
- Support implementation of a national programme to integrate the IT in the 42 laboratories across the country (HSE, 2011).

Development options

To develop a hub and spoke model within a Health Region requires a cooperative approach where one laboratory is designated as the central hub by the Health Region and all other laboratories designated as the spokes or regional centres. All laboratories should work as part of one system in a cooperative and supporting manner. Currently, many laboratories operate as a single entity reporting into its hospital management structure and there is no requirement to network with any laboratory in the hospital group or outside the hospital group. However, it's worth noting that the existence of networks in certain hospital groups, such as the one based on Waterford, which serve as valuable models that demonstrate the feasibility and benefits of inter-laboratory collaboration. The Health Region will need a structure to support this proposed model that would include a laboratory clinical director and laboratory manager on the team for each of the regions. The networking of the central hubs between Health Regions should quickly follow with a national structure to support their work from within the HSE.

In this model, described above, the pathology and laboratory medicine funding will come via the Health Region funding allocation, much the same as is the case now coming through hospital groups. Options for continuing to fund the provision of laboratory services for primary and community care services going forward will need to be reviewed to ensure such services are fully supported and funded.

There are other options for consideration, and they are described below.

Consolidation and Pathology Networks

The 2007 Teamwork Report (Teamwork Management Services Limited, 2007) consolidation of 'cold' work to achieve economies of scale at large centralised testing centres. This recommendation was later reinforced by the Laboratory Modernisation Agreement published in 2011 (HSE, 2011) which again committed to consolidating services within the Public Sector by forming a 'Hub and Spoke' model. Despite the aforementioned reports, consolidation remains largely unimplemented and unrealised. Within the Irish context, any consolidation typically is aligned to the re-organisation of clinical services. Other aspects of modernisation would be consolidation of pathology networks.

Different countries around the world have undergone consolidation of their pathology laboratory services to reduce costs, meet increased demands, and achieve efficiency savings whilst also modernising laboratory infrastructure with new technologies. Despite this, little information has been published on the effects of merging pathology laboratories, in particular financial benefits and efficiencies realised following the implementation of national policies promoting consolidation.

Satta and Edmonstone suggest that the majority of evidence pertaining to consolidation of services within healthcare refers to entire hospitals. Examples include the Mayo and Cleveland Clinics in the United States (US) that have grown through mergers to become some of the most highly regarded hospital systems in the world. More recent evidence from large sample of US hospital mergers between 2000 and 2010 found evidence of economic and statistically significant cost reductions at the acquired sites. University College London Hospitals (UCLH), created in 2004 from the merger of six different hospitals, is the best example in the United Kingdom (UK). Since its inception, they have achieved a strong market share in several key specialties and score highly in national rankings of care quality, patient satisfaction, in addition to their financial performance. However, such savings are associated with the entire organisation and may not translate to efficiencies and cost savings within the pathology departments specifically. Previous reports have suggested that cost-savings are typically in back-office and are from the reduction in management functions as opposed to clinical costs. However. It is believed that pathology departments do benefit from economy of scale and higher purchase discounts in such situations.

It was also noted in an earlier analysis of more than 700 US hospital mergers by McKinsey and the London School of Economics (McKinsey and Co, 2010) that the cost savings achieved were substantially less than originally anticipated. Findings were similar in a study of more than 100 UK hospital mergers (published in 2012) that found many sites' clinical productivity to remain unchanged, their financial performance deteriorate, with none enhancing their quality of care. This, according to Satta and Edmonstone's research, is also confirmed by a report from Norway where they discovered that only one hospital out of 17 (mergers) actually increased its cost efficiency. The authors' research also highlights the following:

Consolidation of Pathology Services in the US

There are several successful examples of diagnostic laboratory consolidation from the US arising from the reimbursement rate decline since 1980 (Clinical Laboratory Fee Schedule). A paper published in 2015 on the consolidation of clinical microbiology laboratories into one network covering 40 different hospitals in North Carolina demonstrated a reduction in test turnaround times in addition cost reductions secondary to economies of scale. This contrasts to earlier evidence suggesting TAT are negatively impacted by consolidation. The impact of consolidation on patient care needs to be evaluated in-depth prior to the implementation of such a network.

Consolidation of Pathology Services in Germany

A prime example of consolidation of pathology services in Europe is in Germany. Approximately 20 years ago, Germany had in the region of 800 pathology laboratories, most of which were publicly funded. Due to running costs, radical reforms were introduced resulting in reduced bed capacity (20%), hospitals (9%), and pathology laboratories (35%). Whilst radical at the time, since this movement, a progressive cost reduction in test tariffs has been realised – 40% of the equivalent of English reference costs for comparable tests. However, in Germany, costs are fixed by the government and competition is based on service quality.

The landscape is now that the majority of District General Hospitals (DGHs) are only equipped with a core laboratory for urgent testing (TAT <2hours) and scientists that are cross trained in various pathology specialties. They exist as part of wider laboratory networks (albeit largely privatised) and with the predominance of five private providers covering up to 60% of the German pathology market.

Consolidation of pathology services in England

In 2018, NHS Improvement for England (NHS, 2018)published a report declaring the following:

"Consolidating pathology services allow for the most consistent, clinically appropriate turnaround times; ensuring the right test is available at the right time. It also makes better use of our highly skilled workforce to deliver improved, earlier diagnostic services supporting better patient outcomes. Taking a 'Hub and Spoke' approach to this consolidation can ensure an appropriate critical mass to support specialist diagnostics, so that patients have equal access to key tests and services are sustainable."

Over the past 15 years, pathology services in England have undergone profound change. The first Carter review published in 2006 (Carter, 2006) highlighted the importance of pathology services to supporting clinical decision making, estimating that 70-80% of all healthcare decisions affecting diagnosis or treatment involve a pathology investigation. Although this statistic has been subsequently refuted by authors in peer-review journals, there is an agreement and understanding that pathology plays a major role in clinical decision making. A further report in 2016 demonstrated the high costs associated with the services when considering referrals from primary, secondary, and tertiary care (£2.5bn/annum). It did, however, state that the price per test varied significantly across England depending on the laboratory with uncontrolled budgeting and rising costs. The proposed solution was a large-scale service consolidation of laboratories with proposed possible savings of £4-5m per network.

In 2008, a second report was published by Carter (Carter, 2008) confirming the strong case for consolidation of pathology services to improve quality, responsiveness, patient safety and efficiency, with a hub and spoke model proposed. At the central 'Hub' the majority of non-urgent tests would be performed, whilst District 'Spokes' would process and report urgent samples. The forecasted annual saving for the entire service was in the region of £250-500m.

To analyse the forecasted savings generated by the move in England, Satta and Edmonstone under the Freedom of Information Act used a questionnaire to obtain cost information for consolidated hubs and non-consolidated laboratories over two time periods – 2010 and 2015. Their findings demonstrated that some of the annual forecasted savings were realised when adjusting for inflation and increased activity, however, stated that further robust research was required to determine whether consolidation truly does result in cost savings. It did note that not all laboratories in both groups (consolidated and non-consolidated) realised savings. This point was emphasised by the President of the Royal College of Pathologists (UK) in 2017 (RCPath, 2017)when they stated:

"It is clear that consolidation doesn't always save money, at least not in the short term. All the features of successful reconfigurations have required significant investment, often in new buildings."

Other impacts from the consolidation of services included:

- Opportunity for the private sector to enter the market (reaching 13% of the market).
- Increased redundancies (0.75%).
- Transfer of employees (25% of workforce were transferred to another institution).
- Increased retirement and individuals leaving the profession.

Consolidation of Pathology Services in Northern Ireland

The Northern Ireland Pathology Modernisation Strategy proposal included three strands:

- Consolidation of cold activity into five hubs.
- Infrastructure development including a new LIMS, sample collection and transport, and maximising the use of technology across the network.
- Integrated management structure.

It is noted that the conclusion by the Health and Social Care Board (HSC) published in 2017 (HSCB, 2017) was *"that pending wider configuration of HSE in Northern Ireland it is not appropriate to move fully to a hot/cold split as proposed"*. However, they are supporting opportunities that may develop in the meantime to identify and consolidate cold work services where possible, such as histopathology.

They have also decided to move ahead with infrastructure developments, such as, a LIMS for the region and the introduction of digital pathology and a new regional management structure. For the latter, a document-Pathology Blueprint Programme has been published as part of a further stakeholder engagement to agree the best way forward for a new management structure and operating model.

Pathology Management Structures

Based on a recommendation from a commissioned report in 2008, Wales has developed a National Pathology Programme Board to bring together clinical directors and directorate managers from each health board, as well as representatives from the Royal College of Pathologists, Institute of Biomedical Scientists, and the Welsh government (Chief Scientific Advisor-Health). The aim of this board is to provide a space to provide a national opinion on the operational and strategic elements of laboratories across the nation.

At a similar time, there was a reorganisation of the healthcare organisations in Wales with the development of seven Health Boards responsible for primary, secondary, and community care. These boards, according to Dr Youd (writing in the same RCPath Bulletin Publication), allowed services, including pathology, to be redesigned to best serve the local population. As an example, non-acute services such as histopathology and microbiology have largely been consolidated onto one site per Health Board.

She also notes that some pathology disciplines are best suited to a single service nationwide, e.g., genetics, which is achievable in Wales through the strong network relationships between Health Boards and the central commissioning ability from the Welsh government. Blood sciences continues to be delivered at each acute hospital site with little appetite for consolidation. This extends to non-urgent testing due to the ongoing need to provide blood science services (including transfusion) at every hospital site. The Welsh government are committed to not closing any of them. Additionally, there is a push to treat patients within their local community and prevent unnecessary admissions to hospital. Even traditional non-urgent testing by GPs is now often required within a few hours or at least before surgeries close so that GPs can make decisions about the need to admit to hospital or treat at home. Outside of blood sciences, Wales has analysed various approaches to centralising and establishing networks for immunology, histopathology and microbiology but have been finding a solution to that difficult to agree on.

In Northern Ireland, as briefly alluded to above, there have been a number of reports and approaches to look at consolidation of pathology services and changes to management structures. However, the most recent document, Pathology Blueprint Programme-referenced above has been published as part of a further stakeholder engagement to agree the best way forward for a new management structure and operating model. They set the rationale out as thus:

"The Pathology Blueprint Programme sets out to explore options for moving the management of laboratory services from each Trust into a single regional pathology management structure, along with the entirety of the NIBTS, and the functions of the NI Pathology Network.

The programme will work with all stakeholders to co-produce an outline design for a single regional pathology management structure, along with a recommendation on the best option for hosting it. This recommendation will be submitted to the Department of Health and Minister for approval in 2023.

The purpose, as stated by HSC, is that pathology services need to be equipped to meet the growing challenges and demands that they face, and to resolve them through a regional approach. Doing so will help to reduce unnecessary duplication, increase consistency and standardisation of laboratory practices, and provide staff with attractive career and development opportunities."

Options to Improve the Delivery of Laboratory Medicine Services in Ireland

It would be important to understand the new clinical and corporate structures for delivering the Sláintecare programme in advance of choosing the best management structure to deliver pathology and laboratory medicine services locally, regionally, and nationally. This could be achieved as part of the setting up of the proposed Regional Health Area (RHAs) as occurred similarly in Wales or variations to that, e.g., as proposed in Northern Ireland.

In terms of the structure, the following should be considered:

1. The development of pathology networks, using the 'Hub and Spoke' model, across RHAs.
   a) The scope of services for each "spoke" (essential services) laboratory to be agreed in consultation with all relevant stakeholders at that site based on quality parameters.
2. Managed service contracts should be considered for all equipment and processes across the network to ensure standardisation, minimal variation, and improved efficiencies.
3. An appropriate ICT infrastructure supporting the development of a laboratory network:
   a) One LIMS system for the entire network, whether implemented regionally or nationally.
   b) Appropriate order communications for primary and secondary care – safety requirement.
   c) Availability of a unique patient identifier to ensure quality of access and patient safety.
4. A national LIMS solution with a single laboratory database for all patient test results is **the preferred solution**. The strategic goal is to *ensure Irish healthcare* providers have 24-hour access to complete and up-to-date accurate laboratory data across *all sites i.e., a national electronic laboratory record*. Such a LIMS system must have modules capable of supporting all the clinical laboratory disciplines and emerging technologies. In the event that a national LIMS is not achievable, then the alternative must be designed to achieve the same goals. As an example, a regional system within each Health Region and pathology network is the minimal that is required with all interfacing to a national system, either a national EHR system or a national laboratory database.
5. Order communications availability from primary care, secondary care and referring clinical entities (e.g., external hospitals) that includes the provision of a readable bar-coded analyser-ready patient sample tubes with results being returned to a GP practice management system for a GP, an external hospital laboratory information management system (LIMS) for an external laboratory and to the local EPR/EHR system and other internal hospital clinical systems as appropriate.
6. Sample collection strategies for OPD patients and GP patients need to be considered beyond the current systems. For example, using the network of pharmacies, available community health centres and shopping malls, etc., for sample collections (including phlebotomy), based on a clinical request followed by stabilisation of samples (if required) is one option that could be examined.
7. In order to support the development of pathology networks, enhanced transport logistics must be implemented, whether regionally or nationally. These should be considered during any implementation plan.
8. Demand optimisation strategies such as "Choosing Wisely" to be constantly updated and promulgated to all professional practices that use laboratory services. Data mining and statistics would help to review patterns of testing versus benchmarks.
9. National laboratory services and reference laboratory services also require a structure for their designation, where they should be located and ensuring they are supported appropriately on the basis of international benchmarks. The availability of such services to patients and their clinicians must be equal across the country.

Appendices

Appendix 1: Legislation and Governance

Legislative Context

The provision of healthcare and the practice of medicine are highly regulated in Ireland, as in most developed societies. Citizens elect representatives, who enact laws to protect citizens. In relation to laboratory services, the relevant Irish Legislation are the Health Acts 1947 to 2007 (including the Medical Practitioners Act, 2007) and the Health and Social Care Professionals Act 2005 as amended.

The practice of medicine **is not defined in these Acts, however is generally considered to encompass** the clinical prevention, diagnosis or treatment of a human disease, injury or condition. The Medical Practitioners Act, 2007 limits the practice of medicine to registered medical practitioners, with the following exceptions:

The practitioner is a dentist registered under the **Dentists Act 1985** who only practises medicine in the course of, and for the purpose of, the lawful practise of dentistry,

The practitioner is a person registered under the **Nurses Act 1985** who practises medicine in the course of, and for the purposes of, the lawful practise of nursing or midwifery,

The practitioner is a registered pharmaceutical chemist or a registered dispensing chemist and druggist, under the Pharmacy Acts 1875 to 1977, who only practises medicine in the course of, and for the purposes of, the lawful practise of pharmacy in accordance with those Acts,

The practitioner is a person registered under the **Health and Social Care Professionals Act 2005** to practise a profession designated under that Act who only practises medicine in the course of, and for the purposes of, the lawful practise of that profession,

The practitioner only practises medicine in the course of rendering first aid to a person,

The practitioner only practises medicine in the State pursuant to the provisions of **Section 50**, (which permits short term practice by registered medical practitioners from another EU member state provided certain criteria are met),

The practitioner only practises medicine in any combination of any of the circumstances specified in *paragraphs (a)* to *(f)*.

Advanced practice in many scientific disciplines involves duties currently undertaken by registered medical practitioners, and therefore, regardless of practice in other jurisdictions, is likely to be deemed to be practicing medicine by the Medical Council, the regulator charged with overseeing the Medical Practitioners Act, 2007. It is important that such developments are considered in line with an appropriate legislative framework, training, certification, registration, regulation, governance, and review. Such a process has been undertaken with the development of advanced nurse practitioners (ANPs), who are recognised as important senior decision makers, and practice independently with defined pathways for referral to and from the ANP, as well as support when required if patients have unexpected clinical issues outside the ANPs scope of practice.

Training

Training of all healthcare professionals to ensure competence is essential to ensure that patients receive safe and effective care. Training should develop the knowledge, skills, attitudes, and behaviours to perform the required task or provide a particular service. Assessment usually includes an element of competency assessment, and this must include assessment of the clinical or laboratory skill, as well as the associated Entrustable Professional Activities (EPA). EPAs are defined as a unit of professional practice that a trainee can be trusted to perform without direct supervision once sufficient competence has been demonstrated. Training bodies delivering training for independent or largely autonomous practice are assessed by and usually accredited by the regulator, involved in regulating the professional activity for which trainees are being trained.

Training should be validated to ensure that the required outcomes are achieved. Transfer of training in one jurisdiction may not fulfil the needs of a similar role in another jurisdiction, depending on legislative requirements, team structure and competency of other team members and governance system. Additional training may be required, as recommended by the appropriate regulator.

Certification

Certification is the objective assessment that competency and associated EPAs have been achieved. Assessment is usually overseen or accredited by the relevant regulatory body. Major changes in assessment usually require approval by the regulator, even between accreditation cycles. When major changes are made without prior approval, the Medical Council has powers to take action to rectify training, which may involve increasing duration of training for trainees affected.

Registration

The Medical Council is the regulator for medical practitioners at all stages of training and competency, including independent specialist practice. The Medical Practitioners Act, 2007 limits the practice of medicine to registered medical practitioners, with some exceptions, detailed in Section 38 of the Act. Of relevance to scientists, *a person registered under the to practise a profession designated under that Act who only practises medicine in the course of, and for the purposes of, the lawful practise of that profession*, is not in breach of the Act.

Where any level of independent practice is considered, this must be underpinned by specialist registration. As an example, specific registration for advanced nurse practitioners was required prior to the roll out of such roles. Specialist Registration became mandatory for medical practitioners in 2008. A small number of medical consultants still do not have Specialist Registration, usually stemming from appointment pre-2008, when specialist registration was voluntary. The HSE has introduced special governance requirements for the support and supervision of those in consultant roles, who do not have Specialist Registration.

A recent HSE HR memo has stated that “It is the aim of the HSE to ensure that all Permanent Consultants are registered on the Specialist Division of the Register”. Independent practice, in the absence of Specialist Registration will open laboratory services to criticism and is likely to be an unwelcome precedent for other professions where the role of specialist registration in ensuring patient safety has been addressed.

Governance

Governance encompasses the system by which an organisation is controlled and operates, and the mechanisms by which it, and its people, are held to account. Ethics, risk management, compliance, and administration are all elements of governance.

Clinical governance may be defined as 'the framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high quality of care'. Improving quality should be a core value of healthcare institutions worldwide; and in the UK following the Health Care Act 1999 there is a statutory 'duty of quality' for healthcare providers. Several clinical governance 'frameworks' or 'pillars' exist, but all focus ultimately on delivering safe, effective, and person-centred care to *every* patient, *all of the time*.

There is a public expectation that the HSE will ensure that the systems, structures, and roles developed enable and ensure that safe effective care is available to all patients. Individual healthcare organisations are responsible for ensuring that the staff and skill mix employed in their organisation can and do deliver safe care to patients. This includes ensuring that all staff are trained and competent for all aspects of their roles and providing additional training and mentoring when gaps are identified.

Clinical governance systems were carefully developed when ANP roles were developed and included a combination of support from nursing management and trainers, and other members of the multi-disciplinary team. A similar approach is essential when considering the enhancement and development of advanced practice within the realms of scientific staff.

Review

Expansion of advanced practice, at any level, requires a carefully constructed pilot, with analysis of outcomes, and incorporation of any required measures. Such a pilot was carried out with ANPs in a number of settings in the health service. The data obtained from the pilot identified issues to be addressed and provided baseline data to inform business cases to develop ANP roles throughout the country. This is a critical step that must not be skipped.

Appendix 2: Funding Bodies

HRB

Applied Partnership Awards (APA)
Fulbright-HRB Health Impact Awards
ERA-NET NEURON Joint Transnational Networking Group Call
HRCI Health Impact Awards 2022
Secondary Data Analysis Projects
DOROTHY Postdoctoral Fellowships in Public Health Crisis
Collaborative Doctoral Awards in Patient-focused Research
Applying Research into Policy and Practice (ARPP) 2022 Fellowships
HRB Postdoctoral Internship Programme
HRCI-HRB Joint Funding Scheme
Investigator-Led Projects
Research Leader Awards (RL)
Summer Student Scholarships (SS)
Emerging Investigator Awards for Health (EIA)

IRC

Government of Ireland Postgraduate Scholarship Programme
Government of Ireland Postdoctoral Fellowship Programme
Enterprise Partnership Scheme (Postdoctoral Scholarships)
Employment-Based Postgraduate Programme

SFI

Royal Society University Research Fellowship
SFI Discover Programme – Opportunistic Funding Mechanism
SFI Frontiers for the Future Awards
SFI Research Centres – Spokes
SFI Strategic Partnerships Programme
SFI US-Ireland R&D Partnership Programme (including Health)
SFI-EPSRC Partnership Rolling Call (EOI to be submitted)
SFI-HRB-Welcome Research Partnership

Charities/Other

Department of Agriculture, Food, and the Marine Funding
Pfizer Global Medical Grants – Investigator Sponsored Research
Einstein Foundation Award for Promoting Quality in Research
ESCMID Research Grants
FUNDING OPPORTUNITIES IN NEURODEGENERATIVE DISEASES
National Institute of Health US Federal Programme

Appendix 3: Technology Matrix

The matrix below was designed to assess new technologies within laboratory medicine.

Clinical and Service Need	• Patient Benefit. • Clinical effectiveness/Clinical Benefit/Operational Benefit.
Technology and Infrastructure	• Technology integration requirements/additional ICT support/system security. • Interconnectivity – remote access for support – remote access for external services e.g., Hospital and GP services – Order Comms facility, both internal and external. • Interoperability – do the systems speak to each other as they should. • Functionality – e.g., the feasibility of data mining for national reporting/research, etc. • Infrastructure Requirements – supporting technology, physical space, associated IT (workstations, PC, etc.). • Training Requirements.
Human Resource	• Training requirements/Education and training – both internal and external. • Expertise/Interpretative expertise. • Increased testing volume/increased/reduced workload due to new technology/ efficiency versus investment/automated versus manual testing.
Clinical Governance	• Quality assurance requirements/investment/existing governance in place. • How to ensure appropriate governance in AI technology. • Audit/Risk management. • Availability of standards for emerging technologies.
Overarching Cost/Benefit	• Benefit for pathology services – cost/saving. • Benefit for the health system – cost/saving.
Implementation Considerations	• Centralised/distributed roll-out. • Lead in time for implementation. • What additional implementation considerations are required? • Turnaround timeframes – consideration of local versus centralised service model depending on the urgency of test result.
Existing Examples	• Are there existing services in Ireland using this technology – if so, can the benefits be determined. • Are there other countries similar to Ireland using this technology – what benefits to that currently used in Ireland can be determined, in particular, cost/benefit analysis. • What is the international best practice example, and how does this compare to the Irish approach currently.

Appendix 4: LIMS

Clinical and Service Need	**Patient Benefit**	A comprehensive and consolidated national laboratory patient record available to clinicians at point of care.
	Clinical Effectiveness	Wider availability of results to healthcare providers supported by paperless e-ordering and resulting. Enhanced clinical audit and faster access to results. The application includes decision support capabilities, visibility of requests and results to streamline care pathways.
	Service Benefit	Comprehensive and robust hosting and technical infrastructure. A full audit and management reporting capability in line with modern information governance standards as applied to health systems globally. National systems facilitate health services to predict workload and spend, enabling preventative healthcare going forward.
Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	Connectivity and interoperability with other clinical systems and electronic health records based on interoperability standards including HL7, standardised coding e.g., LOINC, nationally agreed catalogues and datasets.
	Infrastructure Requirements	Cloud hosted or infrastructure as a service (IAAS) with comprehensive disaster recovery consideration.
	Training Requirements	Mandatory training for all users and user types as part of user registration and access.
Human Resource	**Expertise**	Delivery and support team comprised of experienced healthcare professionals including clinical directors, laboratory managers, medical scientists, clinical scientists, data analysts, ICT technical experts, project managers and project officers.
	Volume and Workload Implications	Management reporting suite included within MedLIS.
Clinical Governance		Local clinical governance applied at each local laboratory. A national clinical directory and clinical advisory group within Programme Governance.
Existing Examples	**Current National Examples**	N/A.
	International Examples	*Some examples in the UK and Australia associated with consolidation and transformation of pathology services.*
	Comparison of National and International Examples	

Appendix 5: Next Generation Sequencing – Applied to Molecular Pathology

Clinical and Service Need	**Patient Benefit**	The application of NGS to cancer diagnostics is required to meet the growing demand for personalised healthcare for patients with cancer. It allows for improved profiling of a patient's disease allowing better treatment selection. It also allows for the identification of individual sensitivity to drugs which may allow clinicians to avoid adverse effects due to drug toxicity.
	Clinical Effectiveness	Molecular diagnostics is an established route to treatment selection in multiple cancers. NGS is required to meet the need for increasingly complex testing and treatment algorithms. Without sufficient molecular information cancer treatment cannot be optimised or in some cases cannot be prescribed.
	Service Benefit	The adoption of NGS as a diagnostic technology will have benefits for many aspects of cancer diagnosis and treatment. The successful adoption of this technology will require that scientists are appropriately trained to meet the demands of data interpretation and clinical reporting. This development is unlikely to supplant the majority of traditional diagnostics and will need to be delivered as an addition to the current service.
Technology and Infrastructure	**Integration Requirements, Interconnectivity, and Interoperability**	NGS generates extremely large multi-gigabyte raw data sets and smaller results sets. Both the processing of raw data and the tertiary analysis of the resulting data require tools that are not widespread within the Irish health system. Integration with current systems which have not been designed to cope with the volume of data or the interpretative reports necessary for result reporting will be difficult but necessary to ensure successful integration of this technology in routine healthcare.
	Infrastructure Requirements	NGS requires spot access to high powered computational infrastructure and long term storage for large data sets which lends itself to cloud-based analysis. Combinations of cloud and local infrastructure would most likely be required to move results and reports back onto laboratory information systems. Physical space requirements are not significant for the NGS instrumentation however preparing samples for NGS analysis does require additional equipment and an appropriately configured molecular laboratory.
	Training Requirements	It would be necessary to ensure the IT departments have available knowledge and personnel to aid laboratory staff in selecting the appropriate cloud-based solutions to suit local requirements. Instrument training is generally provided by reagent and equipment suppliers and should be relatively straightforward for existing molecular laboratories. Training for the analysis of data (bioinformatics) is not available at present as there is no clinical bioinformatics training scheme in Ireland. A clinical bioinformatics training scheme would be required. Training for the interpretation of data is conducted locally but this does not scale to a national level. Qualifications in molecular pathology (FRCPath) are available and could be used as a suitable post-graduate and experiential qualification.

Human Resource	**Expertise**	Technical expertise for NGS instrument setup can be achieved relatively easily for laboratories with existing molecular services. Interpretative expertise is not easily attained for either the analysis of NGS data or the integration of the results into a clinical report. Data analysis and the interpretation of variants and results is the most highly skilled and difficult aspect of the technology.
	Volume and Workload Implications	The requirement for molecular diagnostics is established as standard-of-care and grows each year. The only technology that allows this approach to scale to the necessary level is NGS. This technology does not replace much of the current laboratory service, rather it allows for scalability.
Clinical Governance		The governance of data analysis from technologies such as NGS resides with the consultant staff who sign the final report. This may prove problematic if the scientific staff are required to take decisions on data and reporting pipelines which are outside of the scope of expertise of the consultant. In effect this creates a blind spot in the analytical process. It would be necessary to ensure that consultant staff are either qualified in the data analysis and technology aspect of the technology or that the responsibilities and areas of independent practice are identified and specified for scientific staff.
Overarching Cost/Benefit		As noted above this is a new area of testing and therefore the expenditure is new. This may result in better selection of treatment for patients, but the overall benefit should be considered in terms of the patient benefit – perhaps through a health technology assessment?
Implementation Considerations	**Timeframe for Roll-out**	For molecular pathology, technology such as next generation sequencing is currently best suited to more centralised roll-out. This is due to the rapidly developing nature of the technology and difficulties in achieving the critical mass of knowledge and expertise to process and analyse the data. However, as these technologies become more automated a more distributed roll-out should be anticipated. Developing analytical and interpretative skills in the area of NGS, molecular diagnostics and bioinformatics is therefore more important than the physical hardware and the lead time for implementation should be considered in terms of the lead time for a training and qualification pathway for the analysis and interpretation of NGS data. A pilot training scheme could be in place within 1-2 years if funded and supported. Qualification of 4 staff grade scientist per annum would be a reasonable goal to meet the current and medium-term requirements for molecular haematology and oncology.

Existing Examples	**Current National Examples**	St James's Hospital (Cancer Molecular Diagnostics Laboratory). Beaumont Hospital (Molecular Diagnostics Laboratory).
	International Examples	HMDS Leeds, Bristol, RCPath – Integrated molecular diagnostics and training scheme. Memorial Sloan Kettering Cancer Centre – Broad scale molecular analysis for cancer world's leading cancer centre for molecular analysis and molecularly targeted clinical trials.
	Comparison of National and International Examples	International centres benefit from training schemes and integrated cancer reporting. A broader range of specialities are also often employed in these laboratories allowing for the development of skills necessary for service delivery. Funding on a case-per-case basis is possibly similar to the UK albeit at a smaller scale.

Appendix 6: Digital Pathology

Clinical and Service Need	**Patient Benefit**	Digital pathology can be used for the following: • Getting or giving expert opinions from international organisations in real time and without risk of losing slides/histological material or damage of the glass slides during transport between laboratories. • Reporting from remote sites. • Training new professionals. • Help attract and retain consultants, doctors in training and young and established laboratory scientists in this field where recruitment rates are at the lowest. • Enhance the storage and archival of images for the purposes of review, multidisciplinary team discussion (MDT), undergraduate teaching, and postgraduate training. • Direct link to research and drug discovery and enhancement of precision medicine.
	Clinical Effectiveness	• Immediate sharing and discussion of images with the clinical pathway. • Benefit of getting a report to review in patient pathway as per the need. • Independent of the physical presence of reporting person on the premises. • Improve accuracy and reproducibility of morphological variables (such as distance(s) to resection margin(s), size of lymph node metastasis in breast cancer, depth of invasion of tumour used for staging and prognostics (e.g., melanoma). • Application of scoring system softwares (for automated assessments) of (as examples): mitotic index using Ki67 I various cancers, used for grading; oestrogen and progesterone receptors positivity, and Her2 immunohistochemical staining (drug and predictive tissue markers in breast cancer); application of the Immunoscore (assessing immune cell infiltrations in colon cancers, CE-IVD software), etc. • More than 60 applications of machine learning/artificial intelligence (ML/AI) have been approved by the US FDA to date, that can be embedded in the digital pathology reporting workflow.

Clinical and Service Need	**Service Benefit**	• Improve quality of slides. • Standardised images and selected fields for the reporting person, with simultaneous display of standard stains and additional staining techniques with side-by side parallel viewing and assessment as well as synchronous assessment of regions of interest. • Transportation via electronic and secure mode, in real time without delay from transport between laboratories, and risk of losing slides/histological material or damage of the glass slides in transit. • Help to attract young professionals to this field. • Training, teaching and multidisciplinary will enhance. • Storage, timely communication, and delivery of results can be enhanced. • Reported DP costs breaking even after two years with a productivity improvement of 15% after one year. • Presumed avoidance of over and under treatments costs as well as laboratory cost savings and gains at a regional level by reduced number of slides re-processing and re-staining.
Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	• This technology can be connected to a laboratory information system with a unique laboratory accession number. • The system can be password protected. • The system can be managed through the device provider network controlled by the existing infrastructure.
	Infrastructure Requirements	• These are specific depending on which digital system you would choose. • Each provider has different specifications for hardware, power, and IT specifications. Accommodation to the laboratory will depend on a number of people you require to use the technology. • Local and national cloud space for storage of the digital images (similar to the Irish national integrated medical imaging system – NIMIS). • Generally, providers do the survey and layout technology specification for the instalment, performance and validation.
	Training Requirements	Same as any other training required to open the laboratory report by the non-laboratory person. This will include password protected login to open the report and slides. Loading of the slides, accessing the images and reporting it will be done only by the laboratory personnel. Storage, network access, and security training will be needed for the in-house IT staff.
Human Resource	**Expertise**	Basic histopathology competency in morphology. Training and practice are provided by the digital pathology provider. Competency and proficiency completed as per the requirement.
	Volume and Workload Implications	This technology will address the recruitment issues in the field of histopathology where morphology reporting is required. It will also address the absenteeism, and increased workload thus spreading up the reporting TATs. Enhance the training, teaching and multidisciplinary meetings communication, and with fewer repeat tests/slides cutting and staining.

Clinical Governance		Pathologists. Morphology laboratory scientists. Laboratory aids. IT experts.

Existing Examples	**Current National Examples**	No laboratory accredited in DP in Ireland, few have invested in scanners for small scale DP use including for MDT discussion and niche reporting.
	International Examples	• US widely used for histopathology, cytopathology and immunohistochemistry. • India widely used for reporting histopathology in remote areas. • Regional DP systems in Northern Ireland (https://www.digitalhealth.net/2022/02/northern-ireland-goes-live-with-digital-pathology-services/, and Scotland (NHS Greater Glasgow and Clyde). • Laboratories in Canada, Israel, Spain, Portugal, Scandinavia, have converted to fully digital reporting.
	Comparison of National and International Examples	It needs to be implemented for reporting and accredited in Ireland. The Royal College of Pathologist London has issued Best Practice Recommendations in implementing digital pathology. https://www.rcpath.org/uploads/assets/f465d1b3-797b-4297-b7fedc00b4d77e51/Best-practice-recommendations-for-implementing-digital-pathology.pdf The College of American Pathologist has also published a document on *"Validating Whole Slide Imaging for Diagnostic Purposes in Pathology – Guideline from the College of American Pathologists"*. https://www.cap.org/protocols-and-guidelines/cap-guidelines/current-cap-guidelines/validating-whole-slide-imaging-for-diagnostic-purposes-in-pathology https://doi.org/10.5858/arpa.2020-0723-CP

Appendix 7: Bioinformatics

Clinical and Service Need	**Patient Benefit**	Bioinformatics is a specific skill set which marries computational and biological analysis and is becoming a critical enabling technology for modern medicine as the volume of data produced annually continues to grow. The main driver for adopting bioinformatics in the clinical setting comes through NGS, which has found application in fields such as genetics, cancer, microbiology, virology, pharmacogenomics, and histocompatibility.
	Clinical Effectiveness	Bioinformatics is a key enabler for multiple recent advances in molecular diagnostics but does not provide a standalone patient benefit. For clinical effectiveness, review the relevant NGS submission.
Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	As per NGS submission(s).
	Infrastructure Requirements	As per NGS submission(s).
	Training Requirements	As per NGS submission(s).
Human Resource	**Expertise**	Bioinformatics requires a highly specialised skill set that can prove difficult to source or cultivate.
	Training Requirements	Training for the analysis of data (bioinformatics) is not available at present as there is no clinical bioinformatics training scheme in Ireland. A clinical bioinformatics training scheme would be required. In the UK, the NHS has a dedicated funding and training scheme for clinical scientists working in bioinformatics.
	Volume and Workload Implications	As per NGS submission(s).
Clinical Governance		As for NGS technology submissions: The governance of data analysis from technologies such as NGS resides with the consultant staff who sign the final report. This may prove problematic if the scientific staff are required to take decisions on data and reporting pipelines that are outside the consultant's scope of expertise. In effect, this creates a blind spot in the analytical process. It would be necessary to ensure that consultant staff are either qualified in the data analysis and technology aspect of the technology or that the responsibilities and areas of independent practice are identified and specified for scientific staff.
Overarching Cost/Benefit		As per NGS submission(s).

Implementation Considerations	**Timeframe for Roll-out**	A pilot training scheme could be in place within 1-2 years if funded and supported. Qualification of four staff grade scientists per annum would be a reasonable goal to meet the current and medium-term requirements; however, this number may increase as the technology becomes more routinely used in clinical care.

Existing Examples	**Current National Examples**	St James's Hospital (Cancer Molecular Diagnostics Laboratory). Mater Hospital (NGS lab). St Vincent's Hospital (Histopathology Laboratory).
	International Examples	UK NHS. https://www.hee.nhs.uk/sites/default/files/The%20Future%20of%20Clinical%20Bioinformaticians%20in%20the%20NHS%20-%20Jul%202021_0.pdf
	Comparison of National and International Examples	International centres benefit from training schemes and integrated cancer reporting. A broader range of specialities are also often employed in these laboratories allowing for the development of skills necessary for service delivery. Funding on a case-per-case basis is possibly similar to the UK, albeit at a smaller scale.

Appendix 8: Cell Therapies

Clinical and Service Need	**Patient Benefit**	Stem Cells/Cellular/Gene Therapies are often described as the 'Future of Medicine'. Like all areas of medicine, it will be a highly regulated future with emphasis on quality, safety, and efficacy. These new treatments are already undergoing clinical trials worldwide. They require new ways of working cross-functionally in healthcare organisations, new skills and competencies and oversight by regulatory authorities (e.g., HPRA, European Medicines Agency, FDA). It is imperative to begin this process of developing local knowledge and expertise now, so that as a healthcare provider, the HSE can offer patients the treatments they expect and deserve in the decade to come.
	Clinical Effectiveness	Our academic partner is NUIG, where institutions such as REMEDI and CCMI are at the forefront of the cellular therapy production revolution throughout Europe. The Clinical Research Facility Galway (CRF) is the link between the academic and the clinical and is responsible for clinical trial management within GUH. The confluence of this expertise has yielded exciting research ideas that have resulted in bringing stem cell therapy to Ireland for the first time via clinical trials. Cellular therapies are a medicinal product, with manufacturing and pharmacovigilance regulated as with any other medicine. Cellular therapies utilise donated human cells and tissue as a starting material, be it bone marrow, adipose tissue, skin cells, etc. Having a quality-controlled, regulated, and licensed supply of starting material is a prerequisite of any medicinal product production process. This is where GBTE's role evolved. GBTE worked closely with REMEDI, CCMI and CRF to develop production and supply strategies to facilitate cellular therapy clinical trials in Saolta, and beyond. GBTE is currently the only HPRA-licensed, hospital-based human tissue procurement organisation in Ireland. This entire process was originally designed by GBTE to support clinical trials and research into cellular therapy that originated in the university and are EU funded. Now, these new types of medicines, which were once part of clinical trials, are moving out of the clinical trials arena and becoming an available treatment option. In addition to overseeing the donation process and regulatory requirements, GBTE has extensive expertise in human tissue storage, thawing and bedside reinfusion to a patient via stem cell transplant. These skills are transferable and adaptable to the requirements for bedside reinfusion of these new cell-based therapies.

Clinical and Service Need	**Service Benefit**	It is beneficial to expand what GBTE has achieved to a national level. Procedures for tissue and cell procurement, validation, training and ensuring compliance with the complicated regulatory requirements (under EU directives on Tissue and Cells, GMP and Clinical Trials) should be standardised at the national level. Setting up GBTE as a national procurement organisation would allow faster implementation and rollout of both new clinical trials and new ATMP medicinal products by leveraging the expertise GBTE already has. Private pharmaceutical companies are bringing cellular therapies to the market. Ireland is one of the leading locations worldwide for pharmaceutical companies. These companies are beginning to set up new manufacturing plants in Ireland and across Europe. They will require access to donated human tissue in order to manufacture their medicines. They will mass produce cellular therapies that are available 'off-the-shelf' and can be given to any patient. If this was done on a national basis it may lend a lot more credence to the HSE in negotiating lower drug prices in return for supply of human tissue. It would also assist the IDA in attracting cellular therapy pharmaceutical companies to establish their manufacturing bases in Ireland. This would likely necessitate a cross-industry working party, including key stakeholders from the HSE, IDA, and national regulators.
Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	The tissue and cell procurement process typically sees interaction between the following departments does not require additional IT systems: • Transfusion/Tissue lab regulatory compliance, licencing, carrying out procedures, donation requirements/donor algorithms, training, controlled temperature storage, bedside thawing and reinfusion of cell therapy products. • Microbiology lab sterility testing. • Virology lab viral screening. • Surgical theatres (theatre managers, sterile services department). • Patient's consultant and their team. • Clinical research staff (if clinical trial setting).
	Infrastructure Requirements	See separate submission on NGS.
	Training Requirements	Lab staff to provide specified training to all involved under the terms of its HPRA licence including: • Consultants. • Other doctors. • Nursing staff.

Human Resource	**Expertise**	You must show competence in collecting sterile tissue/cells in accordance with the EU Tissue and Cells Directive and meet all the requirements specified by the HPRA.
	Volume and Workload Implications	This is a new service that would be rolled out to facilitate access to Advanced Therapy Medicinal Products (ATMPs) in Ireland. This will happen piecemeal over an extended period of time. Or it could be fast-tracked by scaling up what has already been achieved here and make Ireland a world leader in both the manufacture and delivery of nextgen medicine.
Clinical Governance		• Lead scientist. • Pathology consultant (most likely a haematologist) to act as a 'responsible person' and provide clinical oversight on decisions to allow donation of human tissue to proceed. • Additional scientists to help provide the service training/back up to Lead Scientist. • Quality manager operating under a HPRA approved quality management system.
Existing Examples	**Current National Examples**	Galway Blood and Tissue Establishment has HPRA licences for the collection of the following types of human tissue, which are then used to make advanced therapies in clinical trial settings: • autologous bone marrow. • allogeneic bone marrow. • autologous adipose tissue. • allogeneic adipose tissue. Please note that the collection of bone marrow here is significantly different to normal bone marrow draws.
	International Examples	Used worldwide for all cell therapy medicinal products.
	Comparison of National and International Examples	

Appendix 9: Pharmacogenomics

Clinical and Service Need	**Patient Benefit**	Individuals in a population will respond to drug therapies in different ways. Nevertheless, many drugs are currently prescribed as "one size fits all" solutions to specific conditions or illnesses. However, individuals will metabolise drugs differently, and a specific drug dosage may lack efficacy in an individual, interact with other drugs where the patient is taking multiple therapies, or lead to toxic concentrations. Organisations, including the World Health Organisation and the National Institute for Clinical Excellence in the United Kingdom (UK), have recommended a personalised approach to care, particularly in individuals with polypharmacy. Pharmacogenomics (also known as pharmacogenetics) is the branch of science that studies the genetic variation underpinning these differential drug responses in individuals. This is an area of enormous potential growth as we enter the era of personalised medicine, with applications including the treatment of cardiovascular disease, Alzheimer's disease, cancer, and asthma. Genetic variability affecting drug metabolism is common in the population, thought to account for up to 30% of the variability observed in drug response. For example, it is estimated that cytochrome P450 2D6, which is thought to be involved in the metabolism of approximately one-quarter of all drugs, is absent in up to 10% of individuals, depending on the population. Those without the genes encoding this enzyme are at risk of toxicity from many commonly prescribed drugs. Other well-known examples of pharmacogenomics include glucose-6-phosphate dehydrogenase deficiency, where patients risk lysis of their red blood cells (haemolysis) when prescribed certain drugs, warfarin sensitivity and resistance, and malignant hyperthermia. Each drug is metabolised in a specific pharmacokinetic pathway. So, knowledge of an individual genotype for those genes involved in the metabolism of specific drugs would allow therapies to be more tailored to an individual's genotype. The human genome project has shown many associations between drug efficacy and interactions and genetic variability. There is considerable heterogeneity in published studies describing pharmacogenomic effects in clinical populations, hindering systematic review and meta-analysis. Consequently, the uptake of pharmacogenomics has been slow in many countries, although this is likely to change in the coming years. In the UK, for example, the Royal College of Physicians in London and the British Pharmacological Society have recently published a report entitled "Personalised Prescribing", which states that sufficient evidence now exists for the adoption of pharmacogenomics in specific genes and certain drugs (https://www.bps.ac.uk/about/our-campaigns/personalised-prescribing). These societies propose that pharmacogenomics now become routine in certain situations within the National Health Service in the UK.
	Clinical Effectiveness	Genetic variations which influence drug pharmacokinetics in individuals are common. A robust system for screening or targeted screening of the population for genetic variations associated with drug interactions, and toxicity, would allow pharmacists and clinicians to prescribe therapies in a manner which is more tailored to the individual patient while minimising the risk of interactions and toxic effects.

Clinical and Service Need	**Service Benefit**	As pharmacogenomics becomes more widely used in clinical practice in Ireland, technologies for performing these diagnostics would need to be embedded in the healthcare system. Without appropriate investment in equipment, specialist staff training, and infrastructure, the HSE may need to rely on expensive private providers or services in other jurisdictions. Building pharmacogenomic services in Ireland would result in quicker diagnoses of patients and a bank of highly qualified staff who could guide the development of the discipline in the future, all at a reduced cost to the HSE.
Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	Certain technologies relating to pharmacogenomics, such as whole genome sequencing, require specialist diagnostic centres. However, many pharmacogenomics tests are less technically demanding and might best be delivered in existing hospital laboratories. Other jurisdictions, for example, have incorporated genotyping services for pharmacogenomics into existing laboratory disciplines and departments such as clinical biochemistry. It is important to recognise that most drugs will be prescribed and dispensed in the community. Any infrastructure, staffing, or training needs described in this document may need to apply to primary, secondary and tertiary care settings.
	Infrastructure Requirements	Larger hospitals in Ireland will likely need facilities to perform the more routine genotyping services, while specialist centres will perform more specialist work. This will require capital investment in equipment and buildings. Careful thought must be given to how pharmacogenomic data is stored and accessed within the HSE. In other jurisdictions, clear guidelines on genotype-based prescribing have been published. The individual and healthcare provider may need to access the relevant genotype information in the hospital or pharmacy setting, where potential side effects and dosage modification can be considered. There may be a need for a central repository for pharmacogenomic data for citizens and the ability for various healthcare facilities to access these data as required, with due care and consideration given to ethical, legal and General Data Protection Regulation aspects of such service provision.
	Training Requirements	Additional scientific staff will be required to perform the genotyping required to provide pharmacogenomic services in Ireland. Staffing will be required to perform and interpret analyses and to liaise with clinical users on how results might impact patient care. To this end, a mixture of clinical biochemists, clinical scientist and medical scientists will most likely be required. Depending on requirements, training might be incorporated into formal training programmes for scientific staff should such exist in the future. If national IT systems are to be implemented, IT specialists in computer science may need to observe how such databases are configured in other jurisdictions.

Human Resource	**Expertise**	Scientists will require training to deliver pharmacogenomics services in Ireland. The degree and nature of training required will depend on the level of specialisation required at a given centre. Should we be using controlled vocabulary to define competency/expertise at this point? • Independent practitioner. • Technical expertise. • Working proficiency, etc.
	Volume and Workload Implications	Any future pharmacogenomics workload within the HSE will be new work. Although it may be possible in some instances, as described, to integrate pharmacogenomics into existing laboratory frameworks, entirely new resources would be required in terms of staffing, training resource, real estate, and equipment. The use of pharmacogenomics is only going to increase in clinical care in the decades ahead, so any services must be future proofed with anticipated increases in workload built into long-term delivery plans.
Clinical Governance		Depending on the nature of the analysis being performed, clinical governance may be provided by consultants currently working within the HSE, such as clinical biochemists or chemical pathologists. For more complex genomics work, suitably qualified persons might not currently be available within the HSE.
Existing Examples	**Current National Examples**	There are no prominent examples of pharmacogenomics being delivered by HSE hospitals.
	International Examples	
	Comparison of National and International Examples	Pharmacogenomics-based guidelines have been issued in The Netherlands by the Clinical Pharmacogenetics Implementation Consortium and the Dutch Pharmacogenetics Working Group. In countries such as the UK, there is a drive by pharmacologist professional bodies and the Royal College of Physicians to implement pharmacogenomics in the NHS. Although it is unclear if a clear strategy exists for delivering pharmacogenomics services at a practical level in the UK, it is fair to say that standardised laboratory services, including genetics services, are in a far advanced state relative to Ireland. It would seem an opportune time for Ireland to consider and push for adopting pharmacogenomics services. However, it should be borne in mind that appropriate investments in local, regional, and national IT infrastructure, building facilities and equipment and dedicated training programmes for scientists and clinicians will be required. More generally, it is fair to say that Ireland is well behind the curve in preparing for genomic medicine, particularly compared with the UK and their initiatives, such as The 100000 Genome Project.

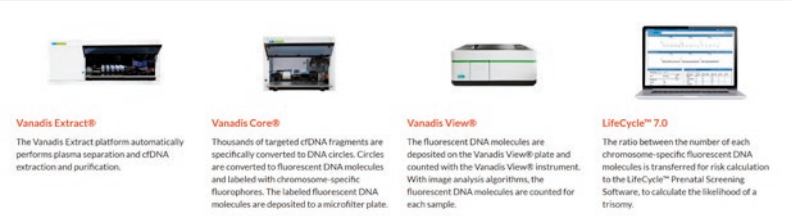
Appendix 10: cfDNA – Applied to Oncology

Clinical and Service Need	**Patient Benefit**	Currently, and with few exceptions, it is necessary to take a biopsy to diagnose and treat cancer. A biopsy is an invasive procedure and can be quite distressing for patients. It may also be the case that multiple biopsies are required in order to ensure sufficient material is available for analysis meaning that patients must undergo multiple procedures to ensure that sufficient information is available to facilitate their care. By using a blood sample to analyse tumour DNA in the circulation (circulating tumour DNA) it is possible to bypass the requirement for biopsy in some settings.
	Clinical Effectiveness	Cell free DNA analysis is already becoming common practice in NIPT and specific use cases in oncology. A more widespread adoption is envisaged which would enable earlier and faster cancer diagnosis and treatment and provide improved options for monitoring minimal residual disease.
	Service Benefit	The adoption of cfDNA analysis would most likely represent an expansion of the existing laboratory services would (potentially) reduce clinical and theatre time and improve patient outcomes. As such, the efficiencies arising from adoption of this technology would be mainly clinical and would require expansion of laboratory services.
Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	This development will, for the most part, be based on next generation sequencing (see separate submission on NGS).
	Infrastructure Requirements	See separate submission on NGS.
	Training Requirements	See separate submission on NGS.
Human Resource	**Expertise**	See separate submission on NGS.
	Volume and Workload Implications	See separate submission on NGS.
Clinical Governance		Pathologists. Morphology laboratory scientists. Laboratory aids. IT experts.

Existing Examples	**Current National Examples**	Isolated application for non-small cell lung cancer (Beaumont, CUH, GUH, SJH).
	International Examples	Guardant 360 is an internationally available comprehensive genomic profiling panel that analyses cfDNA.
	Comparison of National and International Examples	Current use cases for standard-of-care oncology diagnostics, specifically in NSCLC are available in Ireland however the broadening of cfDNA testing in oncology to more genes and more conditions would need to be planned for.

Appendix 11: cfDNA – For the Detection of Fetal DNA in Maternal Circulation

Clinical and Service Need	**Patient Benefit**	Detection of cell free DNA from a fetus in maternal circulation has three specific benefits. Under the termination of pregnancy act fatal fetal anomaly is identified as a reason for termination of pregnancy post 12 weeks. Historically this has been done following taking fluid from around the fetus (amniocentesis) or a piece of placental tissue (chorionic villus sampling) These are invasive procedures. Recently the technique for detection of cell free DNA technology (cfDNA) has been used to detect fetal cfDNA in maternal circulation to screen for trisomy (three copies rather than two) of three chromosomes 13, 18 and 21. These trisomies cause Patau's, Edwards', and Down's syndromes respectively. The first two of these are classified as fatal fetal anomalies. Down's syndrome is not fatal but can also present with severe cardiac anomalies. The simple blood test can detect trisomies at 10 weeks gestation. This test is not analysed in this country at this time. This technology can be used to detect the rhesus D status of a fetus in a rhesus negative mother. Where the fetus is determined as rhesus positive the woman is eligible for prophylactic anti-D at 28 weeks gestation and for all sensitising events to prevent development of haemolytic disease of fetus and new born (rhesus disease or blue baby). If the fetus is considered to be rhesus negative then this prophylaxis treatment is not necessary. This technology can also be used to identify the sex of the fetus which can be important for couples with concerns about diseases such a muscular dystrophy, etc.
	Clinical Effectiveness	Screening for trisomies identifies women who should proceed to confirmatory tests and permits the earlier identification of anomaly and thus earlier termination of pregnancy if desired. The earlier termination is a less complicated surgical procedure. Identification of RhD negative women with RhD positive fetus permits closer monitoring of pregnancy to prevent HDFN and administration of prophylactic anti-D. Fetal anaemia can be prevented and the need for intra uterine transfusion removed.
	Service Benefit	The service benefits are similar to the clinical benefits. The introduction of this technology could be expanded for prenatal diagnosis of other inherited diseases with significant burden of disease such ad haemoglobinopathies, thalassaemia's, congenital adrenal hyperplasia, etc. The expertise would be brought into our own laboratory service rather than the current reliance on a service from the UK with all its attendant instabilities. The service could be introduced as a primary screen or a secondary screen post classification as high risk post biochemical analysis of free beta HCG and PAPPA with ultrasound measurement or a primary screen in its own right negating the resource intensive ultrasound scanning. Consideration should be given to offering this as a national screen or confining to higher risk cohorts.

Technology and Infrastructure	**Integration Requirements, Interconnectivity and Interoperability**	There are two possibilities for introduction of this technology. Next generation sequence systems with significant requirement for bioinformatics with major extraction, amplification and detection systems. This may be difficult to automate to offer as a national screen for all pregnancies. A closed system for the trisomy identification from perkin elmer (Vanadis® system) could be incorporated into a clinical laboratory with minimal informatics capacity. *'With our high-throughput Vanadis® NIPT solution, we're taking all the complexity out of non-invasive prenatal testing, making it accessible to more women – and more cost-effective for your laboratory. This breakthrough cell-free DNA (cfDNA) technology eliminates PCR amplification and gene sequencing, and it's so easy to use that one laboratory technician can handle 2,000 to 20,000 samples per year. Walkaway automation streamlines the process from primary tube to final results. Because the* Vanadis® *system is an easy to use, non-NGS and non-PCR based method, any laboratory can use it.'*
	Infrastructure Requirements	The equipment id not particularly large and could be accommodated in a standard laboratory setting. 
	Training Requirements	Outline training requirements for non-laboratory based personnel or service users. The training required for non-laboratory staff includes understanding of the benefits, risks, and limitations of screening. Women must give informed consent. Counselling staff are needed to deliver reports and discuss options.
Human Resource	**Expertise**	A combination of an advanced practitioner to lead the analytic service with a registered scientist would be able to have the competence to deliver a routine service. Support of a laboratory aide for pre-analytical phase would also be required.
	Volume and Workload Implications	The technology would permit the service to be offered from within the country instead of packaging and tracking the samples to the UK. Reports would be available within our LIMS rather than the difficulties with receiving results from UK labs.

Clinical Governance		Fetal medicine specialists already provide this service however they do not necessarily have the support of genetic consultant and genetic counsellors. A designated advanced practitioner level scientist needs to provide the governance link between laboratory and clinical team. The reports generated give clear indication of risk. The laboratory team members must be part of the MDT managing the service.

Existing Examples	**Current National Examples**	N/A.
	International Examples	CHU Brugmann, Brussels.
	Comparison of National and International Examples	The provision of prenatal genetic screening is well established in Belgium and other European countries. Due to our recent change in our legislation the expertise is not well developed here for an expanded service. New fetal medicine consultant appointments are familiar with requesting these investigations and considering the result implications.

Appendix 12: Microbiology Reference Laboratories

University Hospital Galway – NCPERL

Pathogens: Salmonella, Shigella, Listeria, Carbapenemase Producing Enterobacteriaceae (CPE).

The NCPERL Salmonella, Shigella and Listeria Reference Laboratory service provides the following services:

- Receives and types isolates of salmonella, shigella, listeria and carbapenemase. Producing/Resistant enterobacterales and other resistant bacteria.
- Whole genome sequencing is performed on isolates matching criteria stated in user guide and analysed for various characteristics including sequence type, antibiotic resistance genes, etc.
- Primary role is to determine relatedness between isolates to detect clusters both of pathogens and of specific antibiotic resistance gene containing plasmids.
- Data is shared with users by LIMS report, regular line listings and annual reports.

St James's – GCRL

Pathogens: N. Gonorrhoeae.

The GCRL (interim) provides the following services:

- Reference diagnostics: Antimicrobial susceptibility testing – provision of extended antimicrobial susceptibility testing for Neisseria gonorrhoeae (N. gonorrhoeae), monitoring the high-level azithromycin resistance. Also, to identify and monitor current resistance profiles in Ireland.
- Scientific advice/technical advice to other laboratories that carry out N. gonorrhoea nucleic acid amplification testing.
- Clinical advice to clinicians and laboratories in relation to the diagnosis, treatment, and infection control of N. gonorrhoeae infections.
- Collaboration and research both locally and internationally.
- Monitoring, alert and response in collaboration with the Health Protection Surveillance Centre (HPSC).
- GCRL is a designated laboratory contributing to and participating in the European – Gonococcal Antimicrobial Surveillance Programme (Euro-GASP), providing 200 representative isolate and susceptibility data as part of their annual sentinel surveillance.
- Provision of early warning occurrences to national surveillance body (HPSC) and relevant public health departments.
- Participation and provision of technical advice/expertise in the context of an outbreak.

St James's – NMRSARL

Pathogen: MRSA.

The NMRSARL reference laboratory provides the following services:

- Outbreak investigation/Epidemiological typing of strains to track circulating strains.
- Monitoring of MRSA strains prevalent through the epidemiological typing of isolates submitted to EARS-Net. In outbreak situations spa typing is applied. Whole genome sequencing has been recently introduced for cases where spa typing lacks discriminatory power. WGS has also been utilised to investigate VRE and MSSA recovered from healthcare environments.
- Screening for the presence of virulence factors or toxins.
- Real-time PCR has been utilised to confirm the presence of common resistance determinants including mecA, mecC, cfr, optrA and poxtA in staphylococci and enterococci. For other determinants, the NMRSARL utilises DNA microarray or WGS to investigate isolate. These methods are also applied to the investigation of virulence determinants including PVL, TSST, exfoliative toxins and enterotoxins.
- Antimicrobial resistance monitoring.
- Disk diffusion antimicrobial resistance testing is performed on all S. aureus isolates received for surveillance purposes. Newer antibiotics are investigated using broth microdilution. All isolates are screened for glycopeptide resistance using screening plates, macro-method and if required a modified population analysis profile.
- Investigation of VRE isolates.
- Investigation of enterococci isolates for resistance and outbreak investigations using real time PCR and WGS.

St James's – IMRL

Pathogen: Mycobacteria.

The IMRL reference laboratory provides the following services:

- Provides expertise to laboratories in the diagnosis of M. tuberculosis and other mycobacterial infections.
- It provides a specimen and culture referral service to clinical microbiology laboratories throughout the country. Approximately 5,000 diagnostic specimens are processed annually, with the IMRL receiving approximately 500 mycobacterial cultures per annum for reference tests. These include identification, drug susceptibility testing and epidemiological strain typing using specialised molecular techniques.
- Provides advice to clinicians and laboratories in relation to diagnosis, treatment and infection control of tuberculosis. It works very closely with clinical tuberculosis (TB) services especially supra-regional centre for tuberculosis, to deliver fast and effective treatment for complex tuberculosis cases. This interaction is essential for driving service delivery and research.
- Refers resistant M. tuberculosis complex isolates for additional drug susceptibility testing and refers NTM isolates for drug susceptibility testing as requested by clinical teams.
- Supports teaching and research and endeavours to keep informed of the most recent scientific, clinical and epidemiological trends in mycobacterial infections providing a cost effective and quality assured service.

CHI Temple Street – IMSRL

Pathogen: Invasive Bacterial Pathogens.

The IMSRL reference laboratory provides the following services:

- National PCR diagnostic service for invasive bacterial pathogens (N. meningitides, S. pneoumoniae, H. influenza, S. pyognes, S. agalactiae, S. aureur, E. coli, K. kingeo, L. monocyctogens).
- Syndromic PCR diagnostic service (sepsis, meningitis, bone and joint infections, pleural empyema, deep tissue abscess).
- National WGS-based typing and epidemiology service for invasive bacterial pathogen.
- Reference identification, antimicrobial susceptibility testing, and typing of invasive bacterial isolates.
- Direct typing and characterisation of invasive bacterial pathogens from samples or PCR extracts (e.g., meningococcal typing for potential vaccine coverage).
- 16s sequence-based identification of bacterial isolates (direct characterisation from samples currently being validated).
- Molecular characterisation of bacterial isolates from suspected outbreaks.
- Provision of support to diagnostic laboratories in establishing and troubleshooting bacterial PCR (e.g., investigation of discordant or unusual results).
- Maintenance of nation type culture an dPCR product repository for key invasive bacterial pathogens.
- Provision of expert clinical and scientific advice in relation to the diagnosis and management of bacterial meningitis/sepsis.

National Public Health Laboratory, Cherry Orchard – VTEC NRL

Pathogen: Verocytotoxin E Coli, Campylobacter, and soon C Difficile.

The VTEC NRL reference laboratory provides the following services:

- Surveillance and investigation of outbreaks (e.g., gastro-enteric, legionella, COVID). It is a national reference laboratory site for Verocytotoxin E. coli (2001), Campylobacter spp (2019) and soon C.difficile (tender just awarded), incorporating diagnostic and molecular characterisation services.
- Investigation of public health emergencies e.g., initiating COVID testing and national heater cooler units (HCU) water testing for M. chimaera.

CHI Crumlin – Bordetella pertussis Reference Laboratory

Pathogen: Bordetella Pertussis and Bordetella Parapertussis.

The Bordetella pertussis reference laboratory provides the following services:

- Routine Bordetella pertussis and Bordetella parapertussis real-time PCR and culture on nasopharyngeal aspirate and pernasal swabs.
- Routine B. pertussis IgG testing for infectious status.
- Additional PAN-Bordetella real-time PCR assay covering B. petrii, B. bronchiseptica, B. pertussis, B. trematum, B. hinzii, B. parapertussis and B. holmesii.
- Specific PCR tests available for B. holmessi, B. bronchiseptica.
- VNTR and MLST typing capabilities. NGS based typing under development.
- Pertactin analysis – Pertactin ELISA detection on B. pertussis isolates is available and prn gene mutation analysis is available.
- Future developments – ELISA for detection of toxin and FHA deficient isolates.
- NGS based typing under development.

Appendix 13: Working Group Members

Membership of the Review to Inform the Strategic Direction of Laboratory Medicine Working Group	
Patricia Byron	*Independent Chairperson*
Dr. Siobhan Ni Bhriain	*National Clinical Director of Integrated Care*
Jackie Reed	*National Lead, Health and Social Care Professions*
Breda Rafter	*Principal Officer, Strategic Workforce Planning (DoH)*
Kevin O'Boyle	*Senior Medical Scientist*
Dr. Deirdre O'Brien	*Consultant Microbiologist*
Ciaran Browne	*National Lead, Acute Operations*
Professor Mary Keogan	*Consultant Immunologist*
Marie Culliton	*Scientific Lead, National Clinical Programme for Pathology*
Dr. Jennifer Brady	*Consultant Clinical Biochemist*
Brendan Mullaney	*Principal Clinical Scientist*
Dr. Philippa Ryan-Withero	*Assistant National Director, Strategic Workforce Planning and Intelligence, National HR*
Dr. Cathal O'Brien	*Chief Clinical Scientist*
Dr. Seán Costelloe	*Consultant Clinical Biochemist*
Stephen Power	*Senior Medical Scientist*
Thomas Walsh	*Laboratory Programme Manager*
Eilish Hardiman	*CEO Children's Health Ireland*
Dr. Niall Swan	*Consultant Histopathologist*
John Gibbons	*Laboratory Manager*

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